

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO.,)
LTD.,)
)
Plaintiff,) C.A. No. 21-1015-JLH
)
v.)
)
SAREPTA THERAPEUTICS,)
INC.,)
)
Defendant.)

Monday, May 6, 2024
4:39 p.m.
Teleconference

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE JENNIFER L. HALL
United States District Court Judge

APPEARANCES:

MORGAN LEWIS & BOCKIUS, LLP
BY: AMY M. DUDASH, ESQ.
BY: AMANDA S. WILLIAMSON, ESQ.
BY: WAN-SHON LO, ESQ.
BY: KRISTA VINK VENEGAS, ESQ.
BY: MICHAEL T. SIKORA, ESQ.
BY: DAVID SCHRAEDER, ESQ.
BY: ALISON PATITUCCI, ESQ.

Counsel for the Plaintiff

1 APPEARANCES CONTINUED:

2
3 MORRIS, NICHOLS, ARSHT & TUNNELL, LLP
4 BY: JACK BLUMENFELD, ESQ.
5 BY: MEGAN DELLINGER, ESQ.

6 -and-

7 LATHAM & WATKINS,
8 BY: MICHAEL A. MORIN, ESQ.
9 BY: ERNEST YACOB, ESQ.
10 BY: DAVID P. FRAZIER, ESQ.
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16:39:38 16

16:39:38 17 COURT CLERK: All rise. The United States
16:39:40 18 District Court for the District of Delaware is now in
16:39:43 19 session. The honorable Jennifer L. Hall presiding.

16:39:47 20 THE COURT: Please be seated. All right. We're
16:39:53 21 here for a pretrial conference. This is Nippon versus
16:40:00 22 Sarepta. It's 21-1015.

16:40:04 23 Let's go ahead and put our appearances on the
16:40:08 24 record.

16:40:08 25 MS. DUDASH: Good afternoon, Your Honor. Amy

16:40:11 1 Dudash from Morgan Lewis on behalf of Nippon Shinyaku and NS
16:40:16 2 Pharma. And with me are my colleagues from Morgan Lewis,
16:40:19 3 Amanda Williamson, Shon Lo, Michael Sikora.

16:40:24 4 MR. SIKORA: Hello.

16:40:24 5 MS. DUDASH: David Schrader.

16:40:26 6 MR. SCHRADER: Good afternoon.

16:40:27 7 MS. DUDASH: Krista Venegas. And Alison
16:40:30 8 Patitucci.

16:40:32 9 THE COURT: Good afternoon.

16:40:34 10 MR. BLUMENFELD: Good afternoon, Your Honor,
16:40:36 11 Jack Blumenfeld from Morris Nichols for Sarepta and UWA. We
16:40:41 12 have a number of people here along with me at counsel table.
16:40:44 13 Michael Morin from Latham & Watkins.

14 MR. MORIN: Good afternoon, Your Honor.

16:40:50 15 MR. BLUMENFELD: Next to Mr. Morin, Charles
16:40:50 16 Lipsey and William Raich from Finnegan Henderson.

16:40:54 17 MR. RAICH: Good morning.

16:40:55 18 MR. BLUMENFELD: Behind them, David Frazier and
16:40:56 19 Rebecca Rabenstein from Latham & Watkins. In the first row,
16:41:03 20 Ernest Yacob and Michele Johnson from Latham & Watkins.

16:41:07 21 In the second row, Ryan O'Quinn from Finnegan
16:41:10 22 Henderson. And next to Mr. O'Quinn, Marc Evans and Jessica
16:41:14 23 Driscoll, who are in-house at Sarepta. And I think I'll
16:41:18 24 stop there.

16:41:19 25 THE COURT: Great. Thank you very much. Good

1 afternoon and welcome to everyone.

16:41:21 2 So I can tell you from our side, our team's on
16:41:23 3 its eighth hour in court proceedings today, so we're going
16:41:27 4 to get as far as we can get tonight. If we have to recess
16:41:31 5 and pick it back up on the phone later this week, we'll do
16:41:34 6 that.

16:41:35 7 Our court reporter has been working diligently
16:41:38 8 transcribing some very fast talkers for the last eight
16:41:42 9 hours, so we'll take it nice and slow tonight with the idea
16:41:45 10 that we can pick up whatever we don't finish.

16:41:49 11 All right. Okay. So I have a checklist of
16:42:09 12 things to go through.

16:42:13 13 Why don't we start, while everybody is here,
16:42:18 14 with the MILs, if that make sense, unless you all had a
16:42:23 15 different order you wanted to proceed in.

16:42:27 16 MS. DUDASH: That makes sense, Your Honor.

16:42:29 17 THE COURT: All right. So we have NS MIL No. 1,
16:42:36 18 which has to do with precluding Sarepta from presenting
16:42:40 19 post-priority date evidence in support of its 112 position.
16:42:48 20 Shall we hear argument on that?

16:42:51 21 MS. LO: Thank you, Your Honor. Shon Lo on
16:42:58 22 behalf of Nippon Shinyaku. I believe that our papers set it
16:43:01 23 out, but I think the law is clear and Sarepta does not
16:43:05 24 dispute that compliance with the written description and
16:43:09 25 enablement requirement is determined as of the priority

16:43:12 1 date.

16:43:12 2 And here, their expert, Dr. Dowdy, is relying
16:43:16 3 extensively on post-priority date evidence to validate,
16:43:19 4 confirm, reinforce the inventors' purported discovery. And
16:43:26 5 Nippon Shinyaku submits that that is improper, there's a
16:43:28 6 high risk of confusing the jury and misleading the jury into
16:43:32 7 thinking that that evidence is relevant to the determination
16:43:36 8 of 112 satisfactions --

16:43:40 9 THE COURT: Can you give me your best example of
16:43:42 10 where you think he violates that or would confuse the jury?

16:43:45 11 MS. LO: -- yes, Your Honor.

16:43:47 12 THE COURT: So I don't take them to dispute that
16:43:51 13 the legal standard is that you have to look at 112 as of the
16:43:54 14 priority date. Presumably, they're going to say that for
16:43:57 15 some reason, this evidence is evidence of what a POSA would
16:44:01 16 understand as of the priority date, right? Okay.

16:44:03 17 MS. LO: Actually --

16:44:07 18 THE COURT: Everybody agrees on that, right?

16:44:09 19 MS. LO: I'm sorry, can you --

16:44:10 20 THE COURT: Everybody agrees that the 112
16:44:12 21 inquiry is the priority date -- as of the priority date.

16:44:15 22 MS. LO: Yes.

16:44:17 23 THE COURT: Okay. All right. Where is your
16:44:19 24 best example where they're getting that wrong?

16:44:21 25 MS. LO: I believe it is in Exhibit 1 to our MIL

16:44:24 1 number -- I'm sorry, Exhibit 2 to our MIL No. 1, which is
16:44:30 2 Dr. Dowdy's rebuttal report, specifically paragraph 92 is an
16:44:36 3 example, where Dr. Dowdy states that "numerous researchers
16:44:41 4 independently and repeatedly confirmed that the claimed
16:44:45 5 structural features of the Wilton patents confirmed the
16:44:55 6 claimed function of exon 53 skipping." There's a table
16:44:55 7 appearing, Fig. 13, on page 67.

16:44:58 8 And all of this evidence is post-priority date.
16:45:05 9 And he is relying on it to confirm, validate this hot spot
16:45:12 10 that is supposedly disclosed in the specification of the
16:45:15 11 Wilton patent.

16:45:16 12 Dr. Dowdy also relies on post-priority date
16:45:19 13 evidence to validate the structure function correlation that
16:45:23 14 he claims to perceive in the specification. And he also
16:45:28 15 provides opinions that purport to show recognition of the
16:45:32 16 hot spot by Dr. Wilton and others, even though he has no
16:45:36 17 personal knowledge of what was going through Dr. Wilton's
16:45:39 18 mind or the minds of these other researchers.

16:45:44 19 And I can provide citations to paragraphs from
16:45:48 20 his report, if you'd like.

16:45:49 21 THE COURT: No. That's fine.

16:45:50 22 MS. LO: Okay.

16:45:51 23 THE COURT: Anything else you wanted to add
16:45:53 24 before I hear from the other side.

16:45:54 25 MS. LO: Yes, sorry. And there's also -- not --

16:45:58 1 it's somewhat a complicating factor. But as you know,
16:46:03 2 Sarepta is asserting that the NS patents are obvious. The
16:46:09 3 NS patents have a priority date of 2011. And so he is
16:46:11 4 discussing references between the 2005 filing date of the
16:46:15 5 Wilton patents and the 2011 filing date of the NS patents as
16:46:20 6 reportedly validating, confirming, recognizing the hot spot.
16:46:26 7 And we believe that he should not be allowed to characterize
16:46:30 8 that evidence in that way.

16:46:31 9 We're not seeking to preclude them from relying
16:46:34 10 on the prior art references, obviously, you know, for what
16:46:37 11 they actually disclose or what they actually state. But the
16:46:39 12 way that he discusses them, you know, if he says that, oh,
16:46:43 13 and look, you know, these references validate the hot spot
16:46:46 14 or, look, these researchers recognized from the Wilton
16:46:49 15 specification that there was a hot spot, we feel that that
16:46:53 16 would have an extremely high risk of confusing the jury to
16:46:56 17 think that these references, you know, can support a
16:47:00 18 disclosure of the Wilton patents.

16:47:04 19 THE COURT: Let me ask you this. Couldn't this
16:47:06 20 be handled with a jury instruction that said something to
16:47:09 21 the effect of, you've heard testimony about things that
16:47:14 22 happened after the priority date and you should consider
16:47:17 23 that only to the extent that it's evidence about what a
16:47:21 24 person of skill in the art would have known or recognized as
16:47:24 25 of the priority date.

16:47:25 1 And I could even go further. I could even say,
16:47:28 2 post-priority stuff can only be used to show -- to -- or as
16:47:35 3 evidence of or relevance to what a person would have known
16:47:38 4 as of the priority date for purposes of written description
16:47:42 5 and enablement.

16:47:43 6 Wouldn't that help the jury then to understand
16:47:45 7 what they could use the evidence for?

16:47:47 8 MS. LO: I think it would help the jury but I
16:47:50 9 think that the risk of confusion is really great. These
16:47:52 10 patents are in the same field of research, they both focus
16:47:56 11 on exon 53. And for a juror to kind of separate that out
16:48:01 12 into what, you know, a 2008 reference discloses.

16:48:03 13 And if Dr. Dowdy says, oh, this 2008 reference
16:48:08 14 discloses and confirms that it's the recognition of a hot
16:48:08 15 spot, I think that that's -- there's a high risk that the
16:48:11 16 jurors will just conflate that evidence as improper -- using
16:48:16 17 it improperly.

16:48:17 18 THE COURT: All right. Thank you very much.

16:48:28 19 MR. YACOB: Good afternoon, Your Honor. Ernest
16:48:32 20 Yacob on behalf of Sarepta.

16:48:35 21 The Federal Circuit has repeatedly specifically
16:48:39 22 held that post-priority evidence by a patentee is allowed.
16:48:43 23 That was NS's main argument throughout its briefing. It's
16:48:47 24 wrong.

16:48:47 25 The -- in *Amgen v. Hoechst*, the Federal Circuit

16:48:50 1 accepted numerous post-filing publications demonstrating the
16:48:54 2 extent of the enabling disclosure. That's 314 F.3d at 1336.

16:49:01 3 In *Amgen v. Sanofi*, that's NS's case that they
16:49:02 4 rely on primarily. The Court again -- or the Federal
16:49:07 5 Circuit again allowed such evidence.

16:49:09 6 Quote, "The jury did not hear relevant
16:49:11 7 post-priority date evidence regarding written description
16:49:14 8 and enablement. This evidence may show, for example, that
16:49:18 9 practicing the invention did not require undue
16:49:21 10 experimentation, or that the disclosed species are
16:49:25 11 representative of the claimed genus."

16:49:26 12 That's in the 872 F.3d at 1379.

16:49:31 13 Sarepta's brief includes other examples of
16:49:33 14 Federal Circuit cases holding exactly the same thing. We're
16:49:37 15 happy to go through those, if it's helpful to Your Honor.
16:49:40 16 But Sarepta's post-priority evidence is proper here. It's
16:49:43 17 consistent with the Federal Circuit precedent.

16:49:47 18 Sarepta's patent describes and then claims ASOs
16:49:51 19 that induce exon skipping. The claimed ASOs are
16:49:56 20 structurally defined and they are finite in number. There's
16:50:00 21 no dispute in this case that a person of ordinary skill in
16:50:02 22 the art in 2005 knew how to make those ASOs.

16:50:06 23 What Sarepta is relying on in terms of
16:50:09 24 post-priority evidence is a wealth of direct specific
16:50:14 25 evidence confirming the teachings of the patent. Every ASO

16:50:20 1 that has the structural features that are taught in the
16:50:24 2 patent induces exon skipping.

16:50:30 3 And unlike the few cases that NS does cite for
16:50:35 4 its position, Sarepta is not trying to rely on post-priority
16:50:41 5 evidence as support for new discoveries, new developments.
16:50:46 6 Sarepta is not arguing that the post-priority evidence is
16:50:50 7 proper to show new ASO sequences, new properties of the
16:50:55 8 claimed ASOs.

16:50:58 9 And, you know, to add a layer of, you know,
16:51:02 10 common sense and fair play to all of this, it's NS that
16:51:06 11 introduced the post-priority evidence in the first place
16:51:09 12 through its own testing. What NS is trying to advocate for,
16:51:14 13 and what we submit cannot be right, is this double standard
16:51:18 14 that allows NS to tell the jury half the story, to tell the
16:51:23 15 jury that we've identified a number of embodiments that
16:51:28 16 allegedly do not work. And while precluding Sarepta from
16:51:34 17 relying on any post-priority evidence to refute that
16:51:37 18 contention and show that -- exactly the opposite is true.

16:51:42 19 So for all those reasons, Sarepta submits that
16:51:45 20 the Court should deny NS's motion.

16:51:48 21 THE COURT: Do you have any issue with some kind
16:51:50 22 of an instruction to the extent they're worried about the
16:51:53 23 jury being confused, having an explicit instruction that
16:51:57 24 makes it very clear that they may have seen post-priority
16:51:59 25 date evidence and that that should only be used for the

16:52:02 1 purpose -- 112 purpose of evidencing what a person of skill
16:52:06 2 in the art would have understood as of the priority date?

16:52:10 3 MR. SIKORA: Yeah, I mean, we don't dispute,
16:52:12 4 again, that -- that the evidence we're relying on is for the
16:52:15 5 purpose of illuminating the state of the art as of the
16:52:19 6 priority date.

16:52:19 7 And we also submit that, you know, to the extent
16:52:21 8 NS has any issue with that, they also can cross-examine the
16:52:24 9 witnesses on that point.

16:52:25 10 THE COURT: Okay. Thank you very much. And so
16:52:29 11 my questions may have revealed that we haven't closely
16:52:33 12 parsed the proposed final jury instructions yet. Maybe we
16:52:37 13 would have seen if that was already in there, but we're
16:52:39 14 working as fast as we can. Thank you very much.

16:52:43 15 MR. YACOB: Thank you, Your Honor.

16:52:43 16 THE COURT: So on MIL No. 1, to the extent it
16:52:48 17 requests a blanket exclusion of post-priority date evidence,
16:52:52 18 that request will be denied. If NS wants some type of a
16:53:01 19 curative instruction at the time the evidence is brought
16:53:03 20 in -- I'm not necessarily thinking that's appropriate -- you
16:53:08 21 could propose that to the other side. Or if there's a more
16:53:13 22 specific final jury instruction NS wants to propose, that's
16:53:17 23 something the Court would consider.

16:53:18 24 But to the extent we're asking for a blanket
16:53:21 25 exclusion, that's going to get denied.

16:53:23 1 All right. Let's move on to MIL No. 2 from NS,
16:53:29 2 which has to do with -- I guess, there are four issues that
16:53:32 3 it has to do with.

16:53:37 4 MR. SIKORA: Yes, your Honor. This is Mike
16:53:39 5 Sikora on behalf of Nippon Shinyaku and NS Pharma.

16:53:42 6 So these are four discrete instances where NS
16:53:45 7 and MS Pharma diligently acquired into specific issues that
16:53:50 8 we expect to be frankly, core trial narratives for Sarepta
16:53:56 9 and were stonewalled in discovery.

16:53:58 10 So the first example is how Sarepta chose its
16:54:01 11 accused product beyond it's 53. Ordinarily, you hear
16:54:06 12 defendants describe how they invented their product and how
16:54:09 13 it's amazing when we inquired about the specific selection
16:54:12 14 of the sequence, many of the witnesses said they had no
16:54:16 15 information other than a single sentence read in a document.

16:54:19 16 And when the author of that document, who ran
16:54:21 17 the research project, we had to subpoena her and approach
16:54:27 18 her, you see in the deposition transcripts, Sarepta
16:54:30 19 repeatedly objected on privilege grounds and instructed her
16:54:32 20 not to answer.

16:54:33 21 So for that reason, we don't think, at least in
16:54:35 22 that one, there should be any possibility of Sarepta now
16:54:39 23 introducing a new narrative as to why it selected the
16:54:42 24 product that elaborates beyond that single sentence that was
16:54:46 25 provided in the document.

16:54:47 1 THE COURT: Okay. And my recollection on the
16:54:49 2 papers, at least in my notes, was that they've said they're
16:54:52 3 not going to put on evidence about why it was selected as a
16:54:55 4 final product.

16:54:57 5 MR. SIKORA: If that's their representation,
16:54:58 6 then we think the Court should hold them to that throughout
16:55:01 7 the trial.

16:55:01 8 THE COURT: All right. Thank you very much. Is
16:55:03 9 that the representation?

16:55:10 10 MR. O'QUINN: Ryan O'Quinn for Sarepta.

16:55:15 11 Your Honor, we don't intend obviously to dive
16:55:18 12 into privileged material. The privilege claim here was
16:55:21 13 fairly limited to a single issue. Thousands of pages were
16:55:27 14 produced on the sequence selection issue and five witnesses
16:55:28 15 were made available. So we're not going to present what we
16:55:32 16 withheld from them. We're not going to make a
16:55:36 17 sword-and-shield situation, but we think we should be able
16:55:38 18 to talk about the general development of the product.

16:55:42 19 THE COURT: So let's get to specifics, instead
16:55:45 20 of generalities.

16:55:46 21 Are you going to have somebody say, we selected
16:55:48 22 it as a final product because blank?

16:55:52 23 MR. O'QUINN: We intend to make a presentation
16:56:09 24 consistent with that non-privileged evidence, focusing on
16:56:12 25 that single sentence that counsel has provided. But we

16:56:16 1 don't believe a broad exclusion of evidence is warranted
16:56:19 2 based on this.

16:56:20 3 THE COURT: So just to make sure I understand
16:56:23 4 and I'm not trying to be difficult, I'm just trying to
16:56:28 5 understand.

16:56:28 6 The witness is going to say, we selected it as
16:56:31 7 our final product because we talked to our attorneys and
16:56:36 8 that's what we decided. They're not going to say, because
16:56:39 9 it was the best product because some other reason we haven't
16:56:43 10 heard yet?

16:56:44 11 MR. O'QUINN: That's correct, Your Honor.

16:56:45 12 THE COURT: Counsel?

16:56:47 13 MR. SIKORA: If that's the only statement
16:56:49 14 they're going to elicit, that's fine with us.

16:56:52 15 THE COURT: All right.

16:56:52 16 Are we good?

16:56:54 17 MR. O'QUINN: Yes.

16:56:55 18 THE COURT: Okay. Thank you. Let's move on to
16:56:57 19 part 2B.

16:57:01 20 MR. SIKORA: So this is, it relates to other
16:57:06 21 exon 53 research that Sarepta conducted. Some of this is
16:57:09 22 actually the post-priority date evidence that Dr. Dowdy
16:57:11 23 talks about, was performed by Sarepta researchers, Pierce
16:57:23 24 Thosani and Ryszard Kole.

25 (Reporter clarification.)

16:57:27 1 MR. SIKORA: Pierce Thosani and Ryszard Kole.

16:57:27 2 And Nippon Shinyaku attempted to subpoena these witnesses.

16:57:30 3 Counsel for Sarepta then represented them in opposing those

16:57:36 4 subpoenas. Sarepta itself objected to the subpoenas and

16:57:38 5 they were successful in blocking that discovery.

16:57:41 6 In addition, when Nippon Shinyaku inquired with

16:57:44 7 Sarepta's witnesses that they did make available, including

16:57:48 8 the corporate witness, Dr. Schnell, he disclaimed

16:57:52 9 acknowledge of the design intent behind.

16:57:55 10 And so this is another where, you know, a patent

16:57:57 11 document says what it says, but elaboration beyond that of

16:58:01 12 saying, they were motivated to do this experiment based on

16:58:05 13 Dr. Wilton's work in 2005 or anything else as to why they

16:58:09 14 chose sequences, why they designed all of those to have the

16:58:12 15 length that they did, the complementary that they did, those

16:58:17 16 types of things that -- no Sarepta witness should be

16:58:20 17 speaking to those since we were denied discovery into that

16:58:23 18 and moreover, that should go equally to Sarepta's experts.

16:58:27 19 They shouldn't be speculating on circumstances that there is

16:58:29 20 no evidence in the record regarding --

16:58:31 21 THE COURT: Okay. So I just want to make sure I

16:58:34 22 understand. Dr. Kole and Thosani are not coming to trial,

16:58:40 23 right?

16:58:42 24 MR. SIKORA: That's our understanding, they are

16:58:43 25 not on either parties' witness list and they're outside --

16:58:45 1 THE COURT: So you're worried about one of their
16:58:48 2 witnesses saying, here's why they did what they did?

16:58:51 3 MR. SIKORA: Correct. And the way Dr. Dowdy
16:58:53 4 characterizes it in his report is one of those instances
16:58:56 5 when he describes it -- you know, you heard my colleague
16:59:00 6 describe confirming the 2005 University of Australia work
16:59:05 7 and things like that. There's nothing in the patent that
16:59:07 8 says that they were motivated, for example, by that. And
16:59:10 9 that's just one hypothetical example of something he might
16:59:13 10 say.

16:59:13 11 But if he wants to say, I looked at this
16:59:16 12 reference and this is what the reference says, that's one
16:59:18 13 thing. But trying to infer some other design intent that we
16:59:23 14 were precluding from discovering, shouldn't allowed.

16:59:26 15 THE COURT: Well, Dr. Dowdy doesn't say I talked
16:59:28 16 to these -- Drs. Kole and Thosani, does he?

16:59:33 17 MR. SIKORA: No, he doesn't.

16:59:35 18 THE COURT: Okay.

16:59:35 19 MR. SIKORA: But if he is attributing design
16:59:37 20 intent to what they're doing, rather than factually
16:59:40 21 representing what they did.

16:59:41 22 THE COURT: Okay.

16:59:42 23 MR. SIKORA: That's the line.

16:59:43 24 THE COURT: You don't think he should be able to
16:59:47 25 offer his opinion on what the design intent was based on the

16:59:51 1 records that he looked at and that you have --

16:59:55 2 MR. SIKORA: I don't think he should be able to
16:59:57 3 attempt to speculate as to what was actually in Thosani
17:00:01 4 and -- Dr. Thosani and Kole's mind when they were doing
17:00:04 5 that. I think that's a quintessential limitation on
17:00:08 6 experts, that they shouldn't be allowed to opine on others
17:00:11 7 intents.

17:00:12 8 So if he wants to describe the structure of the
17:00:14 9 research from that objective point of view, that's a
17:00:17 10 different question. I'm referring to why they might have
17:00:20 11 selected ASOs and what they were trying to do with their
17:00:24 12 experimentation.

17:00:25 13 THE COURT: And can you show me -- it's been a
17:00:28 14 long day. Can you show me an example of where he does that
17:00:32 15 in his report?

17:00:32 16 MR. SIKORA: I think the example would be the
17:00:34 17 table that my counsel referred you to. I think it was table
17:00:37 18 13, you mentioned. But it's the characterization of the
17:00:40 19 results. There's a -- accompanying paragraphs that describe
17:00:46 20 the research by Thosani and Kole as confirming the prior
17:00:51 21 research.

17:00:52 22 For example, there's no evidence that what they
17:00:54 23 set out to do in 2008/2009, when they did that
17:01:00 24 experimentation, was reconfirm prior research, for example,
17:01:01 25 right?

17:01:01 1 THE COURT: All right. Thanks very much. I
17:01:03 2 think I understand your position.

17:01:06 3 MR. O'QUINN: Your Honor, we don't intend to put
17:01:10 4 words in the mouth of witnesses that are absent. And we do
17:01:13 5 believe, however, that expert witnesses should be able to
17:01:16 6 interpret what they read from the perspective of a person of
17:01:19 7 ordinary skill in the art, which is all that we seek to do.

17:01:22 8 THE COURT: All right. Yeah. I understand now
17:01:25 9 better having heard from both sides.

17:01:27 10 So this -- this request is also going to be
17:01:32 11 denied without prejudice to re-raise if, for whatever
17:01:35 12 reason, Dr. Dowdy decides to opine on someone's intent.

17:01:48 13 2C?

17:01:49 14 MR. SIKORA: Yes, Your Honor. So this one
17:01:51 15 relates to licensing activity that Sarepta and/or the
17:01:54 16 University of Western Australia engaged in. Many of these
17:01:57 17 agreements were older agreements, focused in, for example,
17:02:00 18 2008, 2013, those sorts of time frames. And there are some
17:02:04 19 instances where witnesses were able to provide testimony
17:02:08 20 about the literal, you know -- you know, what provisions are
17:02:12 21 in the agreement, what scenario is the agreement, you know,
17:02:16 22 prepared for that you can read directly from the agreement.
17:02:19 23 That's fine.

17:02:20 24 What we don't want to see at trial is, for
17:02:22 25 example, a narrative saying, oops, Sarepta approached

17:02:26 1 Dr. Wilton at UWA in 2008 because they recognized his
17:02:29 2 amazing research. When, if that's the case, that testimony
17:02:32 3 was not given. And even though we probed it with both the
17:02:36 4 University of Western Australia and Sarepta's corporate
17:02:39 5 representatives.

17:02:39 6 THE COURT: So just to make sure I understand:
17:02:41 7 You don't want there to be a new story at trial about the
17:02:44 8 background for all these licenses that you haven't heard?

17:02:47 9 MR. SIKORA: Yes, Your Honor.

17:02:48 10 THE COURT: Okay. Thank you.

17:02:50 11 Are we going to hear a new story at trial about
17:02:53 12 the licensing negotiations that they haven't heard?

17:02:55 13 MR. O'QUINN: That is not the plan, Your Honor.

17:02:57 14 THE COURT: Okay.

17:02:59 15 MR. O'QUINN: We're a little worried about the
17:03:01 16 broad scope of what knowledge of negotiations means, that
17:03:03 17 was not part of any discovery that was sought. So we're
17:03:06 18 worried that that could be used to create constant sidebar
17:03:10 19 distractions at trial.

17:03:10 20 You know, the terms of these agreements speak
17:03:13 21 for themselves. Again, the damages experts that will be
17:03:15 22 looking at these have experience in interpreting these terms
17:03:18 23 and we don't believe there should be any limitations on
17:03:22 24 that, but witnesses, obviously, won't be able to go beyond
17:03:25 25 what they said at their deposition in terms of newly

17:03:29 1 acquired knowledge.

17:03:29 2 THE COURT: So this is, again, is going to be
17:03:31 3 denied without prejudice to re-raise if we hear testimony
17:03:34 4 that goes beyond what they said they knew about at their
17:03:41 5 depositions.

17:03:42 6 All right. Damages?

17:03:44 7 MR. SIKORA: Yes, Your Honor. So this relates
17:03:46 8 to a similar issue but for products that experts have --
17:03:50 9 Sarepta's expert have hinted at as being competing products
17:03:54 10 but has been appreciably quantified at least as to this,
17:03:58 11 Elevidys product, which is gene therapy that Sarepta
17:04:02 12 launched with a limited label for restricted age range in
17:04:06 13 June of this year.

17:04:07 14 And so one of the things that was specifically
17:04:11 15 inquired with Sarepta's corporate designee, was how Sarepta
17:04:16 16 had expectations for how follow-on products might effect
17:04:19 17 sales of the accused exon 53 products. And so for one of
17:04:24 18 those products that you don't see in our motion, which was a
17:04:28 19 PPMO 53 product, Sarepta's corporate designee was able to
17:04:33 20 provide a quantitative amount just saying hey, at this point
17:04:36 21 in time, we expected that sales would drop by X percent.

17:04:41 22 Sarepta did not provide that for Elevidys. Even
17:04:45 23 though there were references in the documents to this gene
17:04:48 24 therapy. We diligently inquired with the first corporate
17:04:52 25 representee about what Sarepta's expectations were at the

17:04:55 1 time and how it might effect sales after the product was
17:04:58 2 approved.

17:04:59 3 We, again, inquired with the corporate designee
17:05:01 4 who said that Sarepta did not know. Expert reports came,
17:05:07 5 their expert cited Elevidys as a potential factor but again,
17:05:12 6 did not actually assert that there was some sort of reduce
17:05:15 7 in demand that was going to be captured by this.

17:05:18 8 So if Sarepta created some sort of expectation,
17:05:20 9 it's not in their expert reports, it's not something that
17:05:23 10 was disclosed during fact discovery, and we don't think that
17:05:26 11 they should be allowed to do that as to these other two
17:05:29 12 products that weren't quantified and we didn't get those
17:05:32 13 quantitative financials or anything else to be able to
17:05:36 14 confirm sales data and other things like that.

17:05:38 15 THE COURT: So you don't want a new number at
17:05:40 16 trial, right, but you also don't want them to be able to say
17:05:44 17 generally what they expect the effect would be or that's
17:05:48 18 okay with you?

17:05:49 19 MR. SIKORA: For those products that it wasn't
17:05:51 20 disclosed on, that's correct. So for the one product I
17:05:54 21 mentioned that they did provide that number for PPMO 50, 53.
17:05:58 22 Of course, that's in the record. They disclosed that. We
17:06:01 23 don't have a dispute about that. It's for these other two
17:06:05 24 products for which we did seek information on the products,
17:06:07 25 didn't receive it during fact discovery. Their experts

17:06:10 1 haven't substantively done that. We don't want to see a new
17:06:15 2 narrative at trial that we can't rebut where they all of a
17:06:18 3 sudden say, oh, yeah, we've been launching this product for
17:06:21 4 eight months now and it's been doing great. So yeah, our
17:06:24 5 expectations is that these 53 products are going to go away
17:06:28 6 like that.

17:06:28 7 We don't want to see that type of new narrative
17:06:30 8 from either a fact witness or any of the experts. We'd
17:06:33 9 object based on the scope of their reports, but absolutely,
17:06:36 10 we don't want to hear it from fact witnesses either.

17:06:38 11 THE COURT: All right. Thank you very much.

17:06:43 12 MR. O'QUINN: Your Honor?

17:06:43 13 THE COURT: Do you understand what he's talking
17:06:44 14 about and are you going to do what he's worried about?

17:06:47 15 MR. O'QUINN: I can try to provide a little more
17:06:49 16 context.

17:06:50 17 So Elevidys is a gene therapy product as
17:06:53 18 Mr. Sikora represented, that was approved for a narrow
17:06:56 19 patient population about a year ago. Sarepta has given the
17:07:03 20 best landscape analysis that it has on this issue as of the
17:07:08 21 cutoff time of discovery.

17:07:09 22 This product is still in flux we are still
17:07:12 23 expecting an FDA decision on a potentially expanded patient
17:07:15 24 population in the coming weeks. The reason the witnesses
17:07:18 25 can't give a specific number is because there's no way to

17:07:21 1 know a specific number.

17:07:22 2 But we are worried about the risk, as you raised
17:07:24 3 a moment ago, that general holistic statements about these
17:07:29 4 other products, either at trial, potentially in post-trial
17:07:34 5 briefing are going to be scraped off because of an inability
17:07:37 6 to make a specific number.

17:07:41 7 And -- go ahead.

17:07:42 8 THE COURT: Can you just put a little more
17:07:44 9 detail on it? Explain to me what -- it sounds to me like
17:07:48 10 your witness might say something and so give me an idea what
17:07:52 11 the witness might say.

17:07:53 12 MR. O'QUINN: There isn't a future lost profits
17:07:55 13 claim in this case, so it's not a concern about speculation
17:07:58 14 by the experts as to where the sales will go in the coming
17:08:02 15 years.

17:08:02 16 We don't plan to make a lot about Elevidys in
17:08:06 17 this case. This case is about Vyondys, our product, and
17:08:11 18 Viltепсо, their product. Exondys, the other product that
17:08:14 19 Mr. Sikora mentioned, has a small overlap but isn't a huge
17:08:19 20 factor in this damages case either. So we're just worried
17:08:23 21 that they're again trying to look for an overbroad exclusion
17:08:28 22 on the ground -- we're not planning to come up with a number
17:08:31 23 and say sales will be cannibalized by X%. We can't make
17:08:36 24 that statement.

17:08:36 25 THE COURT: But your witness will say Elevidys

17:08:41 1 is going to affect the sales, we think it's going to affect
17:08:45 2 the sales of the other products?

17:08:46 3 MR. O'QUINN: It's potentially also that the
17:08:49 4 physician witnesses on either side may discuss how that
17:08:52 5 product is affecting prescribing habits. And so that's the
17:08:56 6 fear, is that if we have a broad exclusion of any discussion
17:09:00 7 of Elevidys, you may not get the full picture for the jury
17:09:03 8 of how these patients are being treated. But we're not
17:09:07 9 going to make a categorical statement with a new number at
17:09:10 10 trial that they haven't received.

17:09:12 11 THE COURT: Okay. So when you say the
17:09:13 12 physicians might discuss it, those are your expert witness
17:09:17 13 physicians?

17:09:17 14 MR. O'QUINN: Experts also.

17:09:18 15 THE COURT: And is there anything about Elevidys
17:09:20 16 in the expert reports?

17:09:23 17 MR. O'QUINN: Yes.

17:09:24 18 THE COURT: Okay. All right. And they're not
17:09:26 19 going to testify outside of what they say in the expert
17:09:29 20 reports?

17:09:30 21 MR. O'QUINN: No, Your Honor.

17:09:32 22 THE COURT: All right. Anything else you wanted
17:09:34 23 to add before I hear again from either side?

17:09:34 24 MR. SIKORA: Nothing further, Your Honor.

17:09:35 25 THE COURT: All right. So on that one, again it

17:09:37 1 is going to be denied without prejudice to re-raise in the
17:09:41 2 particular context of the testimony.

17:09:45 3 MR. SIKORA: Yes, Your Honor.

17:09:47 4 MR. O'QUINN: Thank you, Your Honor.

17:09:48 5 THE COURT: All right. So this one has to do
17:09:56 6 with mentioning the IPRs. And so I guess it might be
17:10:14 7 helpful for me to hear from Sarepta first about how you
17:10:22 8 intend to use evidence of the IPRs, and then we can talk
17:10:28 9 about whether or not we think that the prejudice outweighs
17:10:34 10 the probative value.

17:10:38 11 MR. RAICH: Bill Raich of Finnegan, for Sarepta.

17:10:42 12 So the principal use for the IPRs will be to
17:10:46 13 reflect Sarepta's state of mind in response to NS's
17:10:50 14 allegations of willful infringement. So NS put Sarepta's
17:10:55 15 state of mind in play with their allegation of willfulness.
17:10:59 16 Before this litigation, Sarepta filed seven IPR petitions
17:11:03 17 showing its belief that the NS patents are invalid.

17:11:06 18 Further, the PTO's favorable institutions of
17:11:10 19 those proceedings shows the reasonableness of that belief,
17:11:14 20 as the institution requires establishing a reasonable
17:11:17 21 likelihood that the claims are unpatentable.

17:11:21 22 So we think the weight of the authority supports
17:11:23 23 our position that IPR evidence should be considered for
17:11:27 24 willfulness. Now, the cases that NS is relying on are in a
17:11:32 25 posit. Many of them don't address willfulness, or, for

17:11:36 1 example, in the case of Sight Sciences, they involve a
17:11:40 2 denial of institution on discretionary grounds.

17:11:42 3 And I think there's a fundamental difference
17:11:45 4 between a denial of institution and a grant of institution.
17:11:48 5 There are lots of reasons why IPR petitions can be denied.
17:11:52 6 It could be because the examiner already considered the art
17:11:56 7 and it's just exercising their discretion not to go forward.
17:12:00 8 There could be co-pending litigation, so it's a waste of
17:12:03 9 resources. There could be time bars, there could be
17:12:07 10 formality problems.

17:12:08 11 So there's a wide variety of things. I mean, in
17:12:11 12 all of those instances, the board wouldn't have reached,
17:12:14 13 like, the underlying substance of the merits of the
17:12:17 14 decision.

17:12:17 15 But a grant is different. There's only one
17:12:20 16 reason why the IPR petitions are granted. That's because
17:12:23 17 there's a reasonable likelihood that the claims are
17:12:26 18 unpatentable, and this is highly probative of the
17:12:30 19 reasonableness of Sarepta's belief, which undermines NS's
17:12:34 20 allegations of willful infringement.

17:12:36 21 THE COURT: Can I just ask -- I just want to
17:12:38 22 make sure I understand the timeline. Sarepta files the IPRs
17:12:43 23 a couple weeks before this lawsuit begins; is that right?

17:12:51 24 MR. RAICH: Weeks to months before, I don't have
17:12:53 25 the exact, but certainly before the lawsuit began. I don't

17:12:55 1 know the exact time.

17:12:56 2 THE COURT: And then the institution decisions

17:12:58 3 happened after we're in this?

17:13:01 4 MR. RAICH: That is correct, Your Honor. Yes,

17:13:02 5 that is correct.

17:13:03 6 THE COURT: And let me ask you this, if I agree

17:13:06 7 with them that I don't think it's appropriate and would be

17:13:15 8 confusing and prejudicial to the jury that the evidence that

17:13:24 9 the PTAB instituted the IPR, means that the patents are

17:13:32 10 less -- more likely to be obvious -- I think you are

17:13:36 11 tracking what I'm saying.

17:13:38 12 MR. RAICH: I am, yes.

17:13:39 13 THE COURT: You say you still want that evidence

17:13:46 14 to show state of mind. By that, you mean you filed -- you

17:13:49 15 were so convinced as to the invalidity of these patents that

17:13:52 16 you filed the IPR before this litigation even started.

17:13:56 17 MR. RAICH: A good faith belief. Yes, that's

17:13:59 18 right, Your Honor.

17:14:00 19 THE COURT: And do you think that -- I'm not

17:14:02 20 going to be able to articulate this very well. But, what

17:14:07 21 you're going to say is, we couldn't be willful infringers

17:14:12 22 because we thought that the patents were invalid and would

17:14:15 23 get invalidated in the IPRs, except for that I guess the

17:14:19 24 Federal Circuit has already held you shouldn't have been

17:14:22 25 able to file the IPRs to begin with.

17:14:24 1 So you really could have only thought they were
17:14:27 2 invalid based on how it ends up in this litigation, and
17:14:31 3 isn't that the jury that's supposed to be deciding if
17:14:34 4 they're invalid. Do you understand what I'm asking? Isn't
17:14:37 5 it confusing for the jury for you to say we didn't have a --
17:14:42 6 we weren't willful because we thought the patents would be
17:14:45 7 invalid, so we filed the IPR, but you really couldn't have
17:14:48 8 thought that because you weren't supposed to be filing the
17:14:51 9 IPR.

17:14:51 10 Does that make sense?

17:14:53 11 MR. RAICH: I understand the point, Your Honor.
17:14:55 12 I think from our perspective, Sarepta was acting in good
17:15:00 13 faith. Sarepta filed the IPRs, the petitions are
17:15:04 14 reflections of the beliefs of Sarepta.

17:15:06 15 The fact that ultimately based on contractual
17:15:09 16 reasons, you know, there was a Federal Circuit decision
17:15:13 17 overriding the district court's decision findings, having a
17:15:18 18 different interpretation.

17:15:19 19 We just don't think that in any way is
17:15:21 20 meaningful with respect to Sarepta's belief, and in fact,
17:15:24 21 it's a good faith belief that the patents are invalid. We
17:15:27 22 think it's a separate issue.

17:15:29 23 THE COURT: Is there anything I should take from
17:15:31 24 the fact that the IPRs get filed so close in time to when
17:15:34 25 this litigation starts? So we've got opinions from, I

17:15:37 1 think, Judge Bryson and others that say, well, if you file
17:15:40 2 for the IPR after the litigation gets started, it's not
17:15:43 3 really all that probative of willfulness.

17:15:47 4 Here, we just have a couple weeks before. Isn't
17:15:50 5 -- is that more probative --

17:15:52 6 MR. RAICH: I think --

17:15:53 7 THE COURT: -- of nonwillfulness?

17:15:56 8 MR. RAICH: I think if a litigation is upon you
17:15:58 9 and then in response to that litigation, you file IPR
17:16:01 10 petitions, that's a very different situation than filing
17:16:05 11 IPRs before a complaint ever gets filed.

17:16:07 12 And here, keep in mind, it was Nippon Shinyaku
17:16:10 13 that initiated the litigation. And so Sarepta filed its IPR
17:16:15 14 petitions, and then in response to that, Nippon Shinyaku
17:16:19 15 brought suit. But Sarepta's good faith belief existed
17:16:23 16 before the litigation was filed, and I think the IPRs are
17:16:27 17 strong evidence of that.

17:16:28 18 THE COURT: Okay. Thank you very much.

17:16:31 19 Anything you wanted to add before we hear from the other
17:16:35 20 side?

17:16:35 21 MR. RAICH: Just really quickly. I mean, I
17:16:37 22 think this has come up in terms of -- there is relevance to
17:16:41 23 the IPRs that if Nippon Shinyaku argues that the PTO has
17:16:45 24 previously considered the references or references that are
17:16:49 25 cumulative to them, and is making that point, I think it's

17:16:54 1 only fair that Sarepta be permitted to tell the jury that
17:16:56 2 upon a second look the US PTO found that there was a
17:17:00 3 reasonable likelihood that the references would result in
17:17:03 4 finding the NS patents unpatentable.

17:17:05 5 So if they put this into play by relying on what
17:17:08 6 the PTO did and relying on it, I think it's fair to say,
17:17:12 7 well, the PTO actually determined there was a reasonable
17:17:15 8 likelihood that the patents were invalid. That's sort of a
17:17:18 9 second independent play, depending on their actions during
17:17:21 10 the case.

17:17:22 11 THE COURT: All right. Thank you very much.

17:17:24 12 MR. RAICH: Thank you, Your Honor.

17:17:28 13 MS. DUDASH: Your Honor, as you saw from the
17:17:32 14 papers, the Federal Circuit has cautioned against the
17:17:34 15 limited value of PTAB decisions for purposes of willfulness.
17:17:38 16 That's the *SSL Services* case which cites others, that say
17:17:42 17 that the Federal Circuit has warned of the limited value of
17:17:45 18 actions by the PTO to establish a good faith belief of
17:17:48 19 invalidity.

17:17:49 20 This comes up in every case where a party wants
17:17:52 21 to use IPRs for willfulness. Numerous courts, as you
17:17:56 22 mentioned, Judge Bryson, in the *Iogen* case, and numerous
17:18:00 23 other ones cited in our paper, such as Judge Stark's cases,
17:18:03 24 *Integra Life Sciences* court, but I won't go through them
17:18:06 25 all, that have held that it simply is too prejudicial.

17:18:09 1 Even in the cases Sarepta cited, courts said you
17:18:13 2 couldn't say PTAB and IPR because the jury doesn't know what
17:18:16 3 that means. And then it will turn into a sideshow where
17:18:19 4 we'll have to explain that the patent office applies the
17:18:22 5 completely different presumption that invites confusion.
17:18:25 6 That's just simply unnecessary here.

17:18:28 7 One thing we do want to note is we just heard
17:18:32 8 argument just about willfulness. Dr. Dowdy, in his report,
17:18:35 9 as the court is familiar from the Daubert motion, cites this
17:18:39 10 all over the place to say the IPRs confirm his belief of
17:18:42 11 invalidity. That's exactly why there's prejudice here.

17:18:45 12 The jury is going to be confused and think that
17:18:47 13 invalidity must mean a reasonable likelihood, but we all
17:18:51 14 know it's clear and convincing evidence, and that's exactly
17:18:54 15 what the courts have found in excluding this.

17:18:56 16 We would say that we heard a lot about, you
17:19:00 17 know, Sarepta needs this to say that they challenged the
17:19:03 18 patents. If the Court is inclined, we would be willing to
17:19:07 19 say Sarepta could have a statement saying that they
17:19:10 20 challenged the validity of the patents before suit and end
17:19:14 21 it there. No mention of IPR, PTAB, institution decision,
17:19:19 22 which as the Court knows, NS wasn't able to respond.
17:19:22 23 There's no fulsome record.

17:19:23 24 There's a lot of courts that have excluded this
17:19:25 25 kind of evidence simply because the PTAB proceedings were

17:19:29 1 not complete. They had to withdraw them because they were
17:19:31 2 inappropriately filed, which is not an issue we're here to
17:19:35 3 relitigate. The federal circuit already found in our favor
17:19:37 4 on that.

17:19:38 5 But the bottom line is, we don't want this to
17:19:40 6 turn into a sideshow at trial and prejudice us in a way that
17:19:43 7 we think would constitute reversible error.

17:19:46 8 THE COURT: Let me ask you about that last
17:19:48 9 suggestion because that was sort of what I was thinking that
17:19:54 10 maybe the parties could work out. It sounds to me like you
17:19:58 11 might be amenable to it, where they could, say, put on
17:20:02 12 evidence that, yeah, we tried to challenge the patents by a
17:20:06 13 process to go to the PTO and the court later held that that,
17:20:12 14 the obviousness of the patent had to get decided by this
17:20:17 15 court, by this jury, or something like that.

17:20:19 16 MS. DUDASH: I think, Your Honor, we could work
17:20:21 17 something out. Just a statement, when you said put on
17:20:24 18 evidence, I have concerns with making it a sideshow. We
17:20:28 19 could probably work out the contours.

17:20:29 20 But as long as it wasn't going to be explaining
17:20:32 21 the patent office has this procedure, it's called an IPR,
17:20:36 22 here, let me tell you all about it. Because honestly, in
17:20:38 23 the time we're allowed. That's just not going to be
17:20:40 24 possible. And I think, in fairness, that simply is far too
17:20:43 25 confusing for the jury.

17:20:44 1 THE COURT: I understand what you are saying. I
17:20:46 2 will say this. If you're saying that they willfully
17:20:48 3 infringed, they ought to be able to have somebody sit here
17:20:52 4 on the stand and say no, we weren't willfully infringing and
17:20:55 5 we tried to challenge the patents three weeks before and,
17:20:58 6 you know, the Court said we couldn't do it that way, we had
17:21:01 7 to do it here.

17:21:02 8 So you're not precluding that a witness could
17:21:05 9 put on evidence but you just don't want it to go too far.

17:21:08 10 MS. DUDASH: Right, Your Honor. If it was a
17:21:09 11 statement like what you just said, we filed -- we attempted
17:21:13 12 to challenge the patent and it was decided that the jury
17:21:16 13 must decide and here is the reason I, as an expert, think
17:21:19 14 the patent is obvious, which of course will come in, we're
17:21:23 15 comfortable with that with the clear guardrails on. This is
17:21:29 16 not one of those opening-the-door situations.

17 (Reporter clarification.)

17:21:32 18 MS. DUDASH: Sorry.

17:21:33 19 And this is a -- I'm very concerned with
17:21:35 20 prejudice, so this is one area where I know on some of the
17:21:38 21 MILs we've been, you know, we could renew. The minute the
17:21:40 22 jury hears, the prejudice is really incurable.

17:21:44 23 So as long as we had clear guardrails, we are
17:21:46 24 amenable to that. And just a statement that they challenge
17:21:49 25 the patents, not really discussing the patent office.

17:21:52 1 That's exactly what other courts have found. Even when they
17:21:55 2 let this evidence in in different context, needs to be
17:21:59 3 excluded.

17:21:59 4 THE COURT: Understood. Thank you very much.

17:22:01 5 So on this one, I don't like IPRs getting discussed in front
17:22:10 6 of the jury because I agree with the courts that have held
17:22:13 7 that it's confusing and prejudicial, especially in light of
17:22:19 8 the different burdens and additionally, in light of the fact
17:22:23 9 that this is an institution decision and not a final
17:22:27 10 decision.

17:22:28 11 Also problematic here in light of the fact that
17:22:32 12 we've got this contractual provision that the Federal
17:22:37 13 Circuit has said means that Sarepta wasn't allowed to file
17:22:41 14 an IPR, although, again, my decision on this MIL is
17:22:45 15 independent of that.

17:22:48 16 We're not going to allow Sarepta to argue that
17:22:54 17 the PTAB's decision to institute supports Sarepta's view on
17:22:59 18 obviousness. That's not going to happen. I do think that
17:23:07 19 there is some minimal probative value potentially on having
17:23:12 20 Sarepta say that they weren't willful and they tried to
17:23:16 21 challenge these patents. And I'm hearing from NS that
17:23:19 22 they'll work with Sarepta on some guardrails to let that
17:23:23 23 evidence in.

17:23:25 24 So we're not going to have the PTAB's
17:23:28 25 institution decision come in. We're not going to have

17:23:32 1 anything the PTAB did be admitted in support of Sarepta's
17:23:39 2 obviousness opinion. We're going to have a minimal
17:23:43 3 discussion of Sarepta's decision to ask for an IPR as
17:23:52 4 evidence of their non-willfulness.

17:23:55 5 Does anybody have any questions about what I've
17:24:00 6 said?

17:24:02 7 MR. SIKORA: No, Your Honor.

17:24:05 8 THE COURT: All right. Thanks very much. All
17:24:06 9 right. And you should meet and confer to see if you can
10 come to agreement on making sense of the Court's ruling.

17:24:12 11 All right. We're turning to Sarepta's MIL and
17:24:15 12 we're going to start with Sarepta's No. 1, which has to do
17:24:24 13 with patents not in suit. And I'm not sure I 100%
17:24:28 14 understood everything that's going on here, so you might
17:24:30 15 have to walk me through it.

17:24:31 16 MR. RAICH: Yeah, Your Honor, Bill Raich again.
17:24:34 17 So our motion is to exclude evidence of satellite
17:24:39 18 proceedings related to patent other than the patents in
17:24:44 19 suit. And we think the case law overwhelmingly supports
17:24:47 20 exclusion because any possible probative value is outweighed
17:24:50 21 by jury confusion and sort of time wasted.

17:24:54 22 And so in terms of background, NS wants to rely
17:24:58 23 on certain types of information. And the first involve
17:25:03 24 prosecution histories of patent applications and patents
17:25:06 25 that are not related to the patents-in-suit. They are

17:25:10 1 different families, they have different priority dates, they
17:25:12 2 have different specifications, they have claims of different
17:25:15 3 scope. They're not prior art. They're later in time.

17:25:19 4 Many of the statements that they're seeking to
17:25:21 5 rely on relate to other exons, not Exon 53 or areas outside
17:25:27 6 of the Dr. Wilton's hot spot that you're going to hear a lot
17:25:30 7 about.

17:25:30 8 And so we think it's just extremely prejudicial
17:25:34 9 to Sarepta and UWA to have statements taken out of context
17:25:39 10 that were made in really very different situations with
17:25:43 11 different applications, different priority dates, you know,
17:25:49 12 just different claims, et cetera.

17:25:52 13 And so, again, this is, we think, very
17:25:56 14 prejudicial to Sarepta and UWA.

17:25:58 15 And let me give you one example that I think
17:26:01 16 might be helpful. So Nippon Shinyaku argues that Sarepta,
17:26:05 17 in some of these cases, sought claims over the Papawell
17:26:10 18 reference, which is one of the references that we're
17:26:12 19 asserting against the Nippon Shinyaku patent. And they
17:26:17 20 point out that Sarepta made statements that they feel are in
17:26:22 21 conflict with the positions taken in this litigation.

17:26:25 22 THE COURT: What do you mean by Sarepta? Do you
17:26:27 23 mean your -- an expert declaration or do you mean
17:26:30 24 prosecution counsel?

17:26:31 25 MR. RAICH: I mean, prosecution counsel in

17:26:33 1 pursuing -- yeah, good question. Prosecution counsel in
17:26:36 2 pursuing applications in these other families made
17:26:39 3 statements that they would like to use in this case, even
17:26:42 4 though they're very out of context.

17:26:44 5 And they're also ignoring the bigger picture,
17:26:47 6 which is that, although certain arguments were made, the
17:26:50 7 patent office actually rejected Sarepta's arguments. They
17:26:53 8 maintained the obviousness rejections. And Sarepta
17:26:58 9 abandoned those cases. So that information should be
17:27:00 10 excluded. It's really prejudicial and just not relevant to
17:27:05 11 our patent and our case here.

17:27:07 12 And I heard NS's counsel talk about, you know,
17:27:10 13 the time allotted in order to explain things. I think the
17:27:13 14 time allotted to address patents that are so different, that
17:27:19 15 have all of these different issues that would require an
17:27:22 16 incredible amount of context to explain what is going on is
17:27:25 17 a serious problem.

17:27:27 18 THE COURT: You're asking for more than just
17:27:29 19 them not using the statement of prosecution counsel, right,
17:27:31 20 you're also asking for them not to be able to use
17:27:34 21 declarations made by people who are going to be witnesses in
17:27:36 22 this trial?

17:27:37 23 MR. RAICH: I don't think it rises to that
17:27:46 24 level. I don't recall there being specific declarations,
17:27:49 25 but yeah, I am specifically discussing the prosecution files

17:27:56 1 and what happened in those proceedings. So -- I guess the
17:28:04 2 one -- the one, perhaps, exception to that -- and this goes
17:28:08 3 to the second category of evidence that is implicated by
17:28:10 4 this motion, and this relates to the interference, and so
17:28:15 5 it's a little bit different because the interference did
17:28:18 6 involve an application that was related to the Wilton
17:28:22 7 patents-in-suit.

17:28:23 8 But it's a very -- an interference is a
17:28:26 9 specialized proceeding at the US PTO that sort of is a
17:28:31 10 priority contest between that and a different earlier
17:28:35 11 application that was filed earlier and from a different
17:28:39 12 party. So it's a very different procedural posture.

17:28:43 13 And there were statements made by UWA, the
17:28:49 14 University of Western Australia, in the interference
17:28:51 15 proceeding that were made in support of the invalidity of
17:28:54 16 this unrelated patent application from a different entity
17:28:57 17 that's not a party to this suit and that had a different
17:29:00 18 priority date from the Wilton patents.

17:29:03 19 And so any minimal value -- any minimal
17:29:07 20 probative value, such as, you know, statements that they're
17:29:10 21 trying to take out of context is outweighed for the
17:29:12 22 potential for confusion.

17:29:14 23 Now, there's one further, I think, complicating
17:29:17 24 factor, and this actually goes to your question. And that
17:29:21 25 is, UWA's expert in that interference was someone named Matt

17:29:25 1 Wood. And Matt Wood is one of the NS experts in this case.

17:29:30 2 And there's just no reason to bring up his

17:29:34 3 declaration or statements that he made in that interference

17:29:37 4 talking about the different applications there, because he

17:29:41 5 has reports that he's submitted in this case about the

17:29:44 6 patents-in-suit. And we think that he should be limited to

17:29:48 7 offering testimony about the patents-in-suit, not what he

17:29:51 8 said in a different proceeding relating to different patents

17:29:54 9 in a different factual situation.

17:29:57 10 And we -- again, in terms of authority, we think

17:29:59 11 the authority is overwhelmingly in favor of excluding this

17:30:02 12 type of information.

17:30:04 13 And I will be brief, but just to discuss two

17:30:08 14 cases briefly, one is *Solvay v. Honeywell*. This is civ

17:30:15 15 number 06-557-SLR D.I. 329. And there, a motion in limine

17:30:22 16 sought to exclude statements made during the prosecution of

17:30:25 17 a related application -- a related application that

17:30:30 18 characterized the prior art after an examiner had made a

17:30:33 19 rejection. And the case was abandoned. And the Court

17:30:39 20 excluded that satellite proceeding because the marginal

17:30:45 21 relevance was far outweighed by the prejudice involved. We

17:30:48 22 think that that's the case here.

17:30:50 23 And then finally, the one case that they cited

17:30:52 24 in their opposition brief was a case called *Procter & Gamble*

17:30:56 25 v. *Nabisco*. And they cited it for the fact that prosecution

17:31:00 1 admissions are purportedly binding.

17:31:04 2 But there, the Court was discussing admissions
17:31:07 3 made during the prosecution of the patent that was
17:31:10 4 litigated. It was the same patent that was ultimately
17:31:13 5 litigated in the case, not these unrelated applications
17:31:16 6 with, you know, so many differences that would need to be
17:31:20 7 explained.

17:31:20 8 So I hope that's helpful. I'm happy to take
17:31:22 9 questions to try to put this more in context.

17:31:25 10 THE COURT: So I think what would be helpful is
17:31:27 11 so how do you expect this to come in, through the testimony
17:31:30 12 of their experts?

17:31:31 13 MR. RAICH: Yeah, their experts have cited to
17:31:36 14 these prosecution statements and are attempting to try to
17:31:39 15 explain how they are relevant to, you know, the instant
17:31:43 16 cases. And we just think that -- again, that the prejudice
17:31:46 17 substantially outweighs any marginal relevance that might
17:31:49 18 come from the statement.

17:31:51 19 THE COURT: I apologize. Do I have something in
17:31:53 20 the paper about exactly what paragraphs of their expert
17:31:55 21 report you think are going over the line?

17:31:58 22 And the reason why I'm asking is because it
17:32:03 23 would be helpful to me to decide it, but also because they
17:32:06 24 say this is really a move by your side to get out them
17:32:13 25 asking witnesses about declarations that they've made.

17:32:18 1 MR. RAICH: I mean, again, I think this goes far
17:32:20 2 beyond the declarations. And if we don't have a specific
17:32:24 3 paragraph for you, we'll get it to you by the end of this
17:32:27 4 conference or soon thereafter, because it's something that's
17:32:31 5 done substantially in their expert reports.

17:32:34 6 THE COURT: All right. Thanks very much. Let's
17:32:36 7 hear from the other side.

17:32:41 8 MR. SIKORA: So, first of all, Your Honor, to
17:32:44 9 the extent that Sarepta does provide anything later, we'd
17:32:47 10 like a chance to consider those and respond to the extent
17:32:49 11 that they weren't in the briefing.

17:32:51 12 Now, we disagree with counsel's characterization
17:32:53 13 of what is being done here across the board. So I want to
17:32:59 14 start first with the interference proceeding that was
17:33:01 15 mentioned, and then I want to transition over to these other
17:33:04 16 prosecutions of the other Sarepta patents.

17:33:06 17 So the interference involved exon 53 skipping
17:33:12 18 oligonucleotides from another University of Western
17:33:15 19 Australia family member. It involved certain counsel from
17:33:18 20 Sarepta in this room who were arguing factually to the PTAB
17:33:23 21 that the state of exon 53 skipping was unpredictable in
17:33:29 22 2005, continued to be unpredictable all the way through the
17:33:33 23 filing of those briefs, which was in 2014, 2015.

17:33:38 24 Those are party admissions that the University
17:33:41 25 of Western Australia made and that Sarepta made because it

17:33:44 1 was in control of the prosecution history. They were
17:33:46 2 successful in convincing the PTAB to adopt those factual
17:33:49 3 assertions, and they won that proceeding.

17:33:52 4 Then, when the patent-in-suit was being
17:33:54 5 prosecuted, the '851 Patent, Sarepta amended the claims so
17:33:57 6 they were identical to what they ultimately issued as. They
17:34:02 7 were rejected as obvious. And then Sarepta's patent
17:34:06 8 attorney controlling prosecution made virtually identical
17:34:10 9 arguments to those that were made in the interference, cited
17:34:13 10 the same evidence, almost word for word, the citation.

17:34:19 11 And then at the end, made the exact same
17:34:23 12 assertion that it continued, that lack of recognition -- or
17:34:26 13 I'm sorry, a recognition with a lack of unpredictability
17:34:29 14 continued beyond 2005. And again, this is in the
17:34:31 15 prosecution of the asserted patent.

17:34:33 16 And then concluded by saying, by the way, the
17:34:37 17 Patent Trial and Appeal Board already considered this exact
17:34:41 18 issue in this interference. They found the art was
17:34:46 19 unpredictable, and you, patent examiner, should adopt the
17:34:50 20 exact same ruling.

17:34:52 21 The patent office agreed, found the arguments
17:34:55 22 persuasive, withdrew the obviousness rejection. And the
17:34:59 23 asserted patent, having the exact claims that are being
17:35:02 24 asserted against Nippon Shinyaku now, issued.

17:35:05 25 Sarepta now wants to sweep all of that under the

17:35:07 1 rug and say that Nippon Shinyaku cannot mention any of those
17:35:12 2 statements from the interference.

17:35:13 3 And when I say "statements from the
17:35:15 4 interference," I want to be very clear that the use of the
17:35:18 5 interference is for the factual assertions being made.
17:35:22 6 Unlike counsel who represented that they were going to use
17:35:24 7 the IPRs or, in their brief, they mentioned European
17:35:29 8 proceedings for the outcome of those proceedings, we don't
17:35:32 9 intend to argue to the jury that, well, the patent office --
17:35:36 10 the PTAB found this so you should too.

17:35:39 11 What we instead plan to do is highlight the
17:35:41 12 factual assertions being made by the party. Where Sarepta
17:35:45 13 says the art remains unpredictable through 2014, remained
17:35:50 14 unpredictable past 2005.

17:35:52 15 Those party admissions by the patentee before
17:35:55 16 the patent office about a fundamental issue that's central
17:35:58 17 to the 112 issues in this case. Those are the statements
18 that are being used from the interference.

17:36:01 19 And we don't believe that Sarepta has a credible
17:36:04 20 way to argue that they shouldn't come in because they put
17:36:07 21 them at issue in the asserted claim by relying upon them
17:36:10 22 during prosecution of the patent.

17:36:12 23 When we had the meet and confer over this issue,
17:36:14 24 I asked counsel whether or not the statements from the
17:36:17 25 prosecution history where the prosecuting attorney, of the

17:36:21 1 '851 Patent specifically explicitly relied upon the
17:36:24 2 interferences of predictability, whether they intended that
17:36:28 3 to be excluded as well, even though it was in the
17:36:30 4 prosecution history of the asserted patent. They said yes.
17:36:34 5 That's how far they want to go.

17:36:35 6 And I do think the distinction is important that
17:36:38 7 we are focusing on factual party admissions when it comes to
17:36:43 8 unpredictability, when we're talking about interference.
17:36:46 9 Those are fair game. They're not something that are going
17:36:50 10 to require Sarepta to explain the context of the proceeding
17:36:53 11 or anything else. The only thing they will have to explain
17:36:55 12 away is anybody who is in the same position where they make
17:36:58 13 a factual admission and then have to try to explain it away
17:37:01 14 later when it's directly contradictory to their litigation
17:37:05 15 position.

17:37:06 16 That's the only prejudice that they have, and
17:37:08 17 it's not unfair prejudice. That's just having an
17:37:11 18 inconsistent prior party admission.

17:37:13 19 Now, the other set that counsel mentioned, these
17:37:15 20 additional prosecutions, you've heard Bestwick mentioned,
17:37:19 21 you've heard Tonsani mentioned. These are post-priority
17:37:23 22 date research performed by Sarepta, that Sarepta filed
17:37:27 23 patents on, that Dr. Dowdy relies upon as post priority date
17:37:31 24 evidence. But then when Nippon Shinyaku's experts want to
17:37:34 25 rely upon those same applications and the actions Sarepta

17:37:38 1 took with those same applications, now that's out of bounds
17:37:41 2 because, again, Sarepta is making arguments that are
17:37:44 3 inconsistent with its litigation position.

17:37:47 4 So, if it's fair game for Dr. Dowdy to introduce
17:37:50 5 the subsequent research by Sarepta in their patent
17:37:53 6 applications, it should also be fair game for Nippon
17:37:57 7 Shinyaku to then flag to the jury what exactly Sarepta
17:38:00 8 asserted it had invented in those applications and what was
17:38:04 9 patentable over their asserted prior art.

17:38:06 10 And so with those, even though there is some
17:38:09 11 discussion of the specific claims being sought, there is
17:38:12 12 sponsoring expert testimony to put it in context. The jury
17:38:17 13 will be instructed. We've agreed to play the patent video
17:38:20 14 which talks about prosecution. So this is not a situation
17:38:22 15 for those where the jury is going to have to be instructed
17:38:25 16 about other proceedings that aren't already at issue.

17:38:29 17 And so we think that there's a stark difference
17:38:32 18 between the uses that Nippon Shinyaku is using this for and
17:38:35 19 what Sarepta is using this for. And realistically, if they
17:38:41 20 are allowed to use post-priority date evidence, that should
17:38:44 21 open the door to Nippon Shinyaku's reliance to rebut their
17:38:48 22 points, that they're making for invalidity and validity as
17:38:52 23 well.

17:38:53 24 So pause there if you have any questions for me,
17:38:55 25 because I know that was a lot of information.

17:38:57 1 THE COURT: No, I don't. Thank you very much.
17:38:59 2 So I think on this one, what we'd like to do, is take a
17:39:02 3 closer look at it. Not because we think that the issue is
17:39:08 4 particularly challenging to decide, but because we just want
17:39:13 5 to understand exactly what's being objected to.

17:39:16 6 So I'm going to ask Sarepta to let us know with
17:39:19 7 a letter by noon tomorrow which paragraphs exactly they're
17:39:24 8 talking about and we'll take a look at those. And if we
17:39:29 9 need briefing from the parties, we'll ask for it at that
17:39:35 10 point, but just a letter with the paragraphs and no argument
17:39:40 11 would be our preference.

17:39:43 12 And I was mostly tracking, but not 100%, so I
17:39:48 13 think we just need to take some time and I want to get you a
17:39:51 14 good decision.

17:39:54 15 MR. SIKORA: Yes, Your Honor.

17:39:56 16 THE COURT: All right.

17:39:58 17 MR. RAICH: May I briefly respond to a couple of
17:40:00 18 those points?

17:40:01 19 THE COURT: Sure.

17:40:02 20 MR. RAICH: Okay. Thank you.

17:40:09 21 Just a few things about this: First of all, in
17:40:14 22 Category 1, involving sort of the other prosecution cases
17:40:17 23 that are unrelated, you know, if the -- if the jury were to
17:40:23 24 hear arguments about the argument -- if the jury were to
17:40:29 25 hear arguments that were made in those cases by Sarepta in

17:40:32 1 an attempt to get those claims allowed, they would also need
17:40:35 2 to hear that the PTO rejected those arguments and that
17:40:38 3 Sarepta abandoned those cases. I think that's only fair, to
17:40:42 4 provide sort of the full context for what happened there.

17:40:44 5 We think it's much simpler to just preclude this
17:40:48 6 evidence rather than having to go through it but that is
17:40:51 7 certainly fair from our perspective.

17:40:53 8 Second of all, with respect to Dr. Wood, the
17:40:55 9 interference expert, you know he's now their expert and they
17:40:58 10 really shouldn't be given the opportunity to bolster his
17:41:02 11 opinions by saying that he used to be an expert for UWA.
17:41:06 12 That seems, to us, to be prejudicial.

17:41:11 13 A third point, again, this is -- this is very
17:41:16 14 much like the PTAB IPR decisions. They're talking about
17:41:22 15 different proceedings, with different specific issues, all
17:41:25 16 the things that I mentioned about priority dates, claim
17:41:28 17 scope, patent specifications, the types of proceedings, it
17:41:33 18 would take -- it is a very fast, compressed trial with
17:41:36 19 patents going in both directions and we think the time that
17:41:39 20 would be needed to explain all of that, simply would be
17:41:46 21 exceedingly problematic and prejudicial.

17:41:51 22 I think in terms of their statement about what's
17:41:57 23 in the file history, we would be, of course, fine with them
17:42:03 24 citing a specific statement in the 85 -- in the file history
17:42:05 25 of the Wilton patent that's at suit. That's not the issue.

17:42:09 1 But we don't think that that opens the door to all of the
17:42:13 2 briefing and declarations and underlying materials from the
17:42:16 3 interference.

17:42:18 4 So --

17:42:19 5 THE COURT: Thank you very much.

17:42:21 6 MR. SIKORA: Your Honor, if I may briefly, just
17:42:23 7 one or two points?

17:42:25 8 THE COURT: Sure.

17:42:27 9 MR. SIKORA: So first of all, I think it's
17:42:30 10 important to note, if you look at the face of the '851
17:42:33 11 Patent, the references that were provided to the Patent
17:42:36 12 Office during prosecution included the underlying briefing
17:42:39 13 from the PTAB and those were cited to the Patent Office. So
17:42:43 14 this isn't a situation where it's not intrinsic evidence to
17:42:49 15 the asserted patent in that patent's prosecution and in any
17:42:52 16 event, because it's a related family member, it's intrinsic
17:42:55 17 evidence even if Sarepta hadn't specifically cited it in
17:43:00 18 connection with the '851 Patent.

17:43:01 19 So we don't think that that distinction holds
17:43:04 20 water.

17:43:04 21 As to Professor Wood, if their representation is
17:43:08 22 that they are not going to impeach his credibility at all,
17:43:11 23 at trial, then maybe we can discuss the issue that they
17:43:16 24 brought about notifying that he previously worked for
17:43:18 25 Sarepta.

17:43:19 1 But if they do anything to impeach his
17:43:21 2 credibility, it's fair game to point out that he was willing
17:43:24 3 to offer virtually the exact same opinions about exon 53
17:43:28 4 skipping the unpredictable for Sarepta and UWA when they
17:43:33 5 wanted him to.

17:43:34 6 So with that, I'll stop.

17:43:35 7 THE COURT: All right. Thanks very much.

17:43:38 8 All right. We'll take that one under
17:43:42 9 advisement.

17:43:43 10 Let's move on to Sarepta Motion No. 2.

17:43:51 11 MR. MORIN: Good afternoon, Your Honor. Mike
17:43:54 12 Morin on behalf of Sarepta.

17:43:55 13 I think we've said most of what we wanted to say
17:43:57 14 in our papers but if you'd like a little bit more
17:44:01 15 background, both parties and both companies, when they got
17:44:06 16 their products approved, did separate and independent tests,
17:44:10 17 not head-to-head tests but separate tests, to determine the
17:44:15 18 amount of dystrophin increase that their respective products
17:44:19 19 got. They were not comparative, they were with different
17:44:22 20 patient population, they were different studies, different
17:44:25 21 attributes and for that reason, the FDA won't allow either
17:44:28 22 side to make any comparative claims about the efficacy of
17:44:31 23 the two products compared to each other.

17:44:33 24 Flat out-of-bounds and we cited in our brief,
17:44:35 25 their admissions by the 30(b)(6) witness on that, the

17:44:38 1 admissions by their expert on that, the documents that
17:44:42 2 support that. We --

17:44:44 3 THE COURT: And they're not going to do that.

17:44:47 4 MR. MORIN: They say they're not going to do
17:44:49 5 that but in our reply brief, you may have another -- this is
17:44:52 6 on page -- we have a one-page reply brief where we pointed
17:44:55 7 out on page 3, where they say they're not going to try to
17:44:57 8 say that one is better than the other.

17:44:58 9 But on page 2, they cite that they wanted to say
17:45:01 10 that they have the highest dystrophin in levels and if the
17:45:04 11 question is, I'm not allowed to compare myself to Jack,
17:45:07 12 Mr. Blumenfeld, but I'm going to say I'm the tallest of the
17:45:10 13 two of us, you're doing the exact same thing.

17:45:12 14 So they want to say that they have the highest
17:45:15 15 dystrophin levels as compared to us and they say that on
17:45:18 16 page 2 and their expert has said that in their report.

17:45:22 17 What we fear, Your Honor, we have no problem and
17:45:24 18 we'll do the same thing, we have competing patents, Your
17:45:27 19 Honor, so we're seeking lost profits. Your Honor is well
17:45:30 20 aware of lost profits. We have no problem with our friends
21 wanting to get up say they compete with one another, we have
17:45:36 22 safe and effective products and all of that.

17:45:38 23 But the turmoil and the prejudice to us if they
17:45:41 24 suggest in any way that their level of 5% should be compared
17:45:45 25 to our level of 1%, both of which are tenfold increases from

17:45:50 1 the baseline levels with different patient populations, if
17:45:53 2 there's even a suggestion that that shows in any way that
17:45:57 3 theirs is better than ours, which is disallowed by the FDA,
17:46:00 4 and which they say they're not going to do on page 3 but
17:46:03 5 they do on page 2 of their brief, then we have to unwind
17:46:07 6 that because as Your Honor must appreciate any jury is going
17:46:09 7 to look at it and any suggestion that their product is
17:46:12 8 better than ours is going to start affecting who they
17:46:14 9 believe or the innovators here and what's better than what.

17:46:19 10 When it is uncontested, I think, and the FDA has
17:46:19 11 mandated that those comparisons wouldn't mean anything, that
17:46:24 12 they're not the same studies, then they're not comparable
17:46:26 13 and no one is allowed to say it outside of the courtroom, I
17:46:29 14 don't know why they should be allowed to say it inside the
17:46:33 15 courtroom.

17:46:33 16 And we also set forth in -- if your Honor thinks
17:46:34 17 it wouldn't be an issue, I mean, on the possibility that
17:46:36 18 they might do this, that was triggered by some of what they
17:46:39 19 did in the litigation, their expert reports debating, these
17:46:43 20 are different studies and this one had this patient
17:46:45 21 population.

17:46:46 22 None of that should come in front of the jury.
17:46:48 23 They can certainly say they have a safe and effective
17:46:51 24 product. We won't dispute that actually. I think with both
17:46:53 25 sides, there's a two supplier market generally in these exon

17:46:57 1 skippers, that either side can say they're in direct
17:47:01 2 competition and we have lost profits claim, we're going to
3 do the same thing. We can come up and try to prove there
17:47:05 4 are other metrics, ours is better than theirs. No one
17:47:06 5 should be doing that. Both are good, effective drugs,
17:47:08 6 that's all they need.

17:47:10 7 THE COURT: All right. Let's hear from the
17:47:12 8 other side.

17:47:13 9 MR. SIKORA: Just briefly, I just want to
17:47:20 10 reaffirm what your Honor noted, which is that we already
17:47:22 11 stated that we don't intend to draw clear comparisons. The
17:47:25 12 quote that they keep using in their brief, I think is taken
17:47:29 13 significantly out of context, what the expert was opining on
17:47:33 14 if you read that section is not A clinical comparison, it's
17:47:37 15 actually from an economic expert.

17:47:38 16 What the economic expert is rebutting is this
17:47:41 17 allegation that Nippon Shinyaku's ramp-up period in the
17:47:45 18 but-for world, how long it took them to get up to scale,
17:47:49 19 would have taken less time -- or I'm sorry, would have
17:47:52 20 taken -- Sarepta alleged that it would have taken more time
17:47:56 21 for Nippon Shinyaku to do what they did when they ramped up.
17:47:58 22 And the expert was rebutting that by pointing to factors in
17:48:02 23 the market that were not present for the Viltепso product
17:48:06 24 that were present for Vyondys 53.

17:48:11 25 So in Vyondys 53, Sarepta's product in the case,

17:48:12 1 there was a clinical hold -- or I'm sorry, not a clinical
17:48:15 2 hold but a complete response letter issued and the FDA
17:48:19 3 actually deferred judgment and did not approve it right
17:48:21 4 away.

17:48:21 5 So it's about a market perception problem that
17:48:24 6 Nippon Shinyaku did not have to face. That's the crux of
17:48:28 7 the opinion. That's the opinion that would be elicited at
17:48:31 8 trial. It's not -- the opinion never was focused or
17:48:35 9 attempting to prove superiority.

17:48:39 10 So I think if you read the full opinion in
17:48:42 11 context, the goal of the expert, you know, he's not the
17:48:44 12 clinician. If you look at the clinician's report, the
17:48:47 13 clinician doesn't make -- that quote wasn't taken out of the
17:48:50 14 doctor's report, that was taken out of the economics expert
17:48:52 15 report where he's talking about market perception and what
17:48:55 16 led to the ramp-up period.

17:48:57 17 So I think the opinion that he's going to give
17:48:59 18 at trial is not going to be the cherry-picked portion
17:49:02 19 Sarepta relies upon. I can firmly say we don't intend on
17:49:08 20 making explicit compare- -- you know, superiority. The data
17:49:09 21 is what the data is, but we don't intend to make specific
17:49:12 22 comparisons between them.

17:49:13 23 THE COURT: Okay.

17:49:14 24 Go ahead, Counsel.

17:49:15 25 MR. MORIN: Your Honor, I worry when he says

17:49:18 1 clear comparisons and explicit comparisons and he qualifies
17:49:20 2 that. First, my colleagues who are more familiar with the
17:49:23 3 clinical reports as to Dr. Strober, their clinician says
17:49:28 4 physicians could decide Viltепso better based on those
5 numbers.

17:49:32 6 So now if it's one separate move and they want
17:49:33 7 to say we're not saying it's better, we're just saying
17:49:36 8 people could conclude it's better, then you have to unwind
17:49:39 9 it in the exact same way. So maybe we don't have an issue.

17:49:42 10 THE COURT: It doesn't sound like we necessarily
17:49:44 11 do. Do you want to talk -- he's saying his expert's only
17:49:48 12 going to say what's in the report.

17:49:50 13 MR. MORIN: I understand, but maybe we can -- I
17:49:52 14 think if we're on the same page, then there should be no
17:49:55 15 problem with an agreement that no one is not only going to
17:49:57 16 say one is better than the other, but no one is going to
17:50:00 17 suggest that one is better than the other; putting the
17:50:02 18 numbers side by side or saying people might decide on this
17:50:07 19 because it's a higher number. If we're in agreement there,
17:50:09 20 we're fine.

17:50:10 21 THE COURT: Okay. Maybe this is something
17:50:11 22 you-all can work on. I don't want to preclude him from
17:50:15 23 talking about what's in their label either, right, and have
17:50:18 24 you say that they've broken the agreement. So maybe it just
17:50:20 25 has to do with putting them all right next to each other on

17:50:24 1 a split screen.

2 MR. MORIN: It's on a split screen, or this is
17:50:26 3 5, let's turn your label, it's 1; anything like that. Of
17:50:28 4 course, they can talk about what's on their label, but we
17:50:31 5 don't want any suggestion. The little bit of suggestion of
17:50:35 6 any length to a jury, Your Honor, that theirs is better
17:50:38 7 based on that number will take forever to unwind because
17:50:42 8 jurors are going to look at that and could conclude that one
17:50:44 9 is better than the other, which is something the FDA has
17:50:45 10 specifically said, and I think our friends agree, you can't
17:50:49 11 conclude from there. So we should stay away from that.

17:50:50 12 THE COURT: Understood. Is that something you
17:50:51 13 might be able to work with them on?

17:50:53 14 MR. SIKORA: Yes, Your Honor. I think this is a
17:50:55 15 situation similar to earlier ones where, you know, on a
17:50:57 16 case-by-case basis if something crosses the line, I think
17:51:01 17 should be raised with -- you know --

17:51:01 18 THE COURT: With the understanding, though, that
17:51:03 19 we're not going to have any direct comparisons at trial.

17:51:06 20 MR. SIKORA: Right. We do not intend to put
17:51:08 21 them on a slide side by side and say 5.9 is better than .9%.
17:51:17 22 We don't intend to provide that demonstrative.

17:51:20 23 THE COURT: Okay.

17:51:20 24 MR. MORIN: Okay. And hopefully we all agree
17:51:22 25 that it goes beyond providing that demonstrative and it's

17:51:22 1 not -- we just saw five, now let's talk about the other
17:51:25 2 product. This should be not mentioned in accordance with
17:51:29 3 one another.

17:51:30 4 MR. SIKORA: I think this is where it goes to,
17:51:33 5 Your Honor's point, that I'm hesitant to say more because I
17:51:36 6 don't want to preclude us from --

17:51:38 7 THE COURT: Right. I think -- all right. We're
17:51:39 8 going to hear something about -- we're going to hear
17:51:55 9 something from NS's damages expert about ramp-up time. And
17:52:00 10 none of that testimony should be discussing that our product
17:52:04 11 is better or anything like that. That's where we'll leave
17:52:08 12 it. And I think everybody understands how we're going to
17:52:13 13 proceed.

17:52:13 14 MR. MORIN: We do. And just, Your Honor, not to
17:52:15 15 beat a dead horse, and then I will sit down. The reason we
17:52:18 16 brought it as limine rather than Daubert is it could affect
17:52:22 17 anything. You opened and you say, let's look at this label,
17:52:24 18 now let's look at that label, and you start making
17:52:26 19 insinuations, which is why we didn't limit it to a Daubert.
17:52:28 20 It could be cross-examination, it could be all sorts of
17:52:31 21 things. That's why we brought it in this forum, Your Honor,
17:52:34 22 just so you're aware.

17:52:35 23 THE COURT: I understand. All right. So that's
17:52:38 24 resolved.

17:52:41 25 And so now we have Sarepta MIL No. 3.

17:53:03 1 MR. RAICH: Bill Raich again, Your Honor. So
17:53:05 2 I'm going to try to respond, because there was an order that
17:53:09 3 you issued relating to our MIL No. 3, where you indicated
17:53:14 4 that you're considering whether to clarify or amend the
17:53:18 5 construction of base sequence before the case goes to the
17:53:22 6 jury.

17:53:22 7 And I really want to answer your questions in
17:53:26 8 discussing this. Just by way of background, so Sarepta
17:53:30 9 proposed a construction of base sequence that required a
17:53:37 10 100% complementary throughout the entire length of the
17:53:40 11 antisense oligonucleotide. And then Nippon Shinyaku's
17:53:44 12 proposed construction did not. It required only that a
17:53:46 13 portion of the antisense oligonucleotide have a 100%
17:53:52 14 complementary, but there could be another portion that was
17:53:56 15 random basis, for example, under the way that they were
17:54:00 16 interpreting base sequence. And that construction was
17:54:01 17 adopted.

17:54:02 18 Now, we think that clarifying the construction
17:54:05 19 of base sequence to require a 100% complementary through the
17:54:10 20 full length of the antisense oligonucleotide would
17:54:15 21 streamline the written description and enablement issues in
17:54:18 22 dispute.

17:54:19 23 So let me try to explain this. So Dr. Hastings,
17:54:22 24 who is Nippon Shinyaku's expert, argues that the claims are
17:54:26 25 overly broad because they cover oligonucleotides that have

17:54:32 1 random bases or things that fold on themselves instead of
17:54:35 2 binding to the target. And those types of claim scope
17:54:41 3 arguments with a construction that makes it clear that the
17:54:45 4 claim is directed to things that are a 100% complementary
17:54:50 5 through the full length, would eliminate those types of
17:54:53 6 claim scope arguments that allow for the random basis or the
17:54:57 7 self-folding oligonucleotides.

17:55:00 8 Now, she has other arguments that she makes for
17:55:03 9 112 based on, for example, specification, you know, support
17:55:08 10 in the specification for specific claim terms. Those would
17:55:11 11 not be foreclosed by tightening the construction. And so in
17:55:15 12 that sense, NS and Dr. Hastings would be free to make
17:55:19 13 written description enablement arguments on that basis.

17:55:22 14 So we think that a narrowing construction is
17:55:25 15 appropriate and I'll explain why momentarily. But it would
17:55:36 16 be appropriate and it would prevent Dr. Hastings from
17:55:40 17 offering testimony about the scope of the genus to the jury.
17:55:46 18 And so I want to turn now to the construction issues and why
17:55:50 19 we think that the narrowing construction is appropriate.

17:55:54 20 So the construction that NS offered is -- we
17:55:58 21 think it's just wrong. And there are really -- it is wrong
17:56:03 22 on the law and it is wrong on the facts.

17:56:06 23 So in terms of the law, Claim 1 separately
17:56:12 24 requires a bay sequence comprising 12 consecutive bases of
17:56:18 25 seek ID number 195, okay. That's a requirement of the

17:56:22 1 claim. And that sequence, those 12 bases, are 100 percent
17:56:29 2 complementary to the exon 53 target region.

17:56:34 3 So if you say that the bay sequence limitation
17:56:40 4 applies to only part of the claim, only part of the claim
17:56:44 5 needs to be a hundred percent complementary -- excuse me,
17:56:48 6 only part of the oligonucleotide needs to be a hundred
17:56:52 7 percent complementary, there's already part of the claim
17:56:55 8 that requires that, and that's the seek ID number 195
17:56:59 9 limitation. It's already there.

17:57:00 10 So the term, a bay sequence comprising 12
17:57:05 11 consecutive bases of seek ID number 195 renders superfluous
17:57:10 12 the bay sequence that requires a hundred percent
17:57:15 13 complementary throughout the antisense oligonucleotide.
17:57:17 14 Now, scientifically -- oh, one other thing is that Dr.
17:57:21 15 Hastings, Nippon Shinyaku's expert, admits that under that
17:57:26 16 construction, the term is superfluous. She says in her
17:57:31 17 opening expert report at paragraph 45, "Because a bay
17:57:35 18 sequence comprising 12 consecutive bases of seek ID number
17:57:41 19 195 is a hundred percent complementary, the 12 consecutive
17:57:42 20 bases of the target region, as construed by the Court, I
17:57:46 21 interpret the limitation, a hundred percent complementary,
17:57:50 22 to be subsumed by the limitation at least 12 consecutive
17:57:54 23 bases of seek ID number 195."

17:57:57 24 The constructions that render claim terms
17:57:59 25 superfluous are disfavored. So we think that legally that's

17:58:03 1 inappropriate. And scientifically, there's just no
17:58:07 2 publication that describes an antisense oligonucleotide as
17:58:12 3 having two or more bay sequences. You're just talking about
17:58:16 4 the bay sequence of the antisense oligonucleotide.

17:58:20 5 Sarepta's construction, which requires a hundred
17:58:24 6 percent complementary, we think should be adopted. So the
17:58:28 7 specification depicts every antisense oligonucleotide with a
17:58:32 8 single sequence. The understanding of the person of
17:58:36 9 ordinary skill is that in the context of an antisense
17:58:40 10 oligonucleotide there's a correlation between the bay
17:58:42 11 sequence and what the antisense oligonucleotide is.

17:58:47 12 And Nippon Shinyaku's attacks, we think just
17:58:49 13 aren't with merit. Their principal attack on Sarepta's
17:58:53 14 proposed construction involves something called a WEASEL.
17:58:58 15 And a WEASEL is individual oligonucleotides, each of which
17:59:05 16 themselves are a hundred percent complementary, but are then
17:59:08 17 tethered together.

17:59:09 18 It's sort of this separate idea of having two
17:59:12 19 things tethered together by a linker, or three things
17:59:15 20 tethered together by a linker. But it's abundantly clear
17:59:19 21 from the specification that these claims are not intended to
17:59:22 22 cover WEASELS. These claims are limited to things that are
17:59:25 23 20 to 31 nucleotides in length. And the examples in the
17:59:28 24 specification are much longer than that.

17:59:30 25 For example, the only exon 53 WEASEL that's set

17:59:34 1 forth -- and this is at Table 1C, Column 21, is 75
17:59:39 2 nucleotides long or 75 bases long, not 20 to 31. And it's
17:59:44 3 of course perfectly appropriate, claims don't have to cover
17:59:47 4 every single embodiment in the specification. They
17:59:51 5 shouldn't be contorted to do so.

17:59:54 6 Now, just one more point, I think. So in terms
18:00:00 7 of Dr. Dowdy's position on antisense, when they say that the
18:00:15 8 additional bases in the claims antisense oligonucleotide can
18:00:22 9 be random, as Dr. Dowdy explains, that's just fundamentally
18:00:25 10 inconsistent with the plain and ordinary meaning of what an
18:00:28 11 antisense oligonucleotide is.

18:00:32 12 Clarifying that a bay sequence would require a
18:00:35 13 hundred percent complementary throughout the antisense
18:00:41 14 oligonucleotide is consistent, it tightens up Dr. Dowdy's
18:00:44 15 position, the plain and ordinary meaning of an antisense
18:00:48 16 oligonucleotide is something that is highly complementary,
18:00:52 17 if not a hundred percent complementary.

18:00:55 18 The bay sequence construction would further
18:00:57 19 clarify the scope of the claim in a way that's consistent
18:00:59 20 with the plain and ordinary meaning.

18:01:05 21 THE COURT: Don't have any questions. Thanks
18:01:07 22 very much.

18:01:20 23 MS. WILLIAMSON: Your Honor, in preparation, I
18:01:23 24 have prepared some demonstratives for the argument and I
18:01:26 25 actually -- I prepared two different presentations because I

18:01:30 1 wasn't sure of the scope that -- of argument that you wanted
18:01:35 2 and what kind of clarification that you might be seeking.

18:01:39 3 So at the outset, I'd just like to say that if
18:01:45 4 you were to adopt or pursue my colleague's argument that bay
18:01:52 5 sequence should be now reconstrued as 100% complementary,
18:01:56 6 you would be full stop reversing Judge Williams' opinion.
18:01:59 7 It would not be a clarification. It would be a full
18:02:02 8 reversal of his opinion. It is also entirely inconsistent
18:02:07 9 with the arguments that are in the motion in limine.

18:02:10 10 THE COURT: Well, it would be -- it would be
18:02:24 11 clarifying his construction but it certainly would be
18:02:27 12 different than the opinion text right before he announced
18:02:31 13 what his construction was. I can't disagree with that.

18:02:34 14 MS. WILLIAMSON: Yes. So if we could just turn
18:02:37 15 to the MIL presentation.

18:02:43 16 MR. SIKORA: I'm sorry, Your Honor, is there a
18:02:44 17 button that needs to be pressed on your end to permit
18:02:47 18 viewing on the lectern or something?

18:02:48 19 THE COURT: We're working on it.

18:03:00 20 MS. WILLIAMSON: So if we could proceed to
18:03:03 21 slide --

18:03:04 22 THE COURT: I mean, he says -- before you get to
18:03:06 23 that, he says any sequence of bases that is part of the
18:03:10 24 antisense oligonucleotide. And your view is that that means
18:03:22 25 that read in the context of the claim, not the whole

18:03:27 1 antisense oligonucleotide has to be a hundred percent
18:03:31 2 complementary.

18:03:31 3 But his construction doesn't really resolve that
18:03:34 4 issue, but I get that what he said seems to be contrary to
18:03:39 5 what they said in his opinion. And you-all made arguments
18:03:42 6 about this before the Markman hearing and he -- I don't
18:03:46 7 think I can dispute that he appeared to reject theirs and
18:03:50 8 adopt yours, and that your experts proceeded on that basis.

18:03:54 9 MS. WILLIAMSON: Yeah. So actually, could we --
18:03:57 10 so here is the -- the crux of the dispute was whether a bay
18:04:01 11 sequence can be a portion of the claimed oligonucleotide or
18:04:04 12 whether it must include all bases of the antisense
18:04:10 13 oligonucleotide.

18:04:10 14 And the Court found that there was no evidence
18:04:13 15 in the claims, specification or prosecution history, to
18:04:16 16 support limiting a bay sequence to the entirety of the
18:04:19 17 claimed antisense oligonucleotide. That was based in part
18:04:24 18 on several points, if we proceed forward. This is the
18:04:29 19 claim's language here. An antisense oligonucleotide of 20
18:04:36 20 to 31 bases comprises a bay sequence. That is 100%
18:04:42 21 complementary. And two of the key parts of the claim
18:04:45 22 language to Judge Williams' opinion are the comprising
18:04:48 23 terms, obviously, and the term "a" base sequence with the
18:04:53 24 article "a".

18:04:55 25 And he found that indeed the patentee chose to

18:04:59 1 recite "a" base sequence as a separate claim term from
18:05:05 2 antisense oligonucleotide. If Your Honor were to find the
18:05:07 3 entire sequence 100% complementary, you would be conflating
18:05:11 4 the term antisense oligonucleotide with the base sequence.
18:05:15 5 So it would no longer be an antisense oligonucleotide
18:05:20 6 comprising a base sequence among other things, it would be
18:05:24 7 just that one thing.

18:05:27 8 And so that is a construction that is highly
18:05:32 9 disfavored in the Federal Circuit. The claim -- sorry.
18:05:37 10 This is what we see when we adopt Sarepta's language, that
18:05:43 11 20 to 31 bases comprising a base sequence that is 100%
18:05:47 12 complementary, that portion of the claim is literally
18:05:50 13 omitted. It's just deleted.

18:05:53 14 And it becomes an antisense oligonucleotide of
18:05:57 15 20 to 31 bases that is 100% complementary. If that's what
18:06:02 16 Sarepta had wanted, that's what Sarepta should have claimed
18:06:05 17 in the first place. But they elected a comprising claim,
18:06:08 18 which is different than the NS claims that are at issue in
18:06:13 19 this suit.

18:06:14 20 We elected a consisting of claim. They elected
18:06:17 21 a comprising of claim and then they had named elements after
18:06:21 22 that included a base sequence.

18:06:28 23 So as the Court found, the plain language of the
18:06:32 24 claim suggests the claimed antisense oligonucleotide
18:06:35 25 includes a base sequence that meets subsequently recited

18:06:38 1 limitations. The claim language does not require the
18:06:42 2 claimed antisense oligonucleotide, consists only of the
18:06:46 3 recited base sequence.

18:06:54 4 So then we look to the next -- so in addition to
18:06:57 5 reading out comprising, Sarepta's construction also reads
18:07:03 6 out "a" or "an", which is an open meaning term, and suggests
18:07:07 7 additional portions. So "a" base sequence plus another base
18:07:14 8 sequence.

18:07:15 9 So there is no language in the claims or the
18:07:18 10 specification that necessitates a departure from the general
18:07:21 11 rule, which is what the Court found, that as a matter of
18:07:24 12 law, one would read a base sequence as a part of the
18:07:28 13 antisense oligonucleotide.

18:07:31 14 In addition, when we go through the other
18:07:35 15 factors, we also see -- and this is part of a list of
18:07:37 16 problems with Sarepta's proposed construction. It reads out
18:07:41 17 comprising, it would conflate two claim terms so it doesn't
18:07:47 18 give them their full meaning, and the construction renders
18:07:51 19 that term superfluous.

18:07:53 20 So my colleague said their construction
18:07:57 21 preserves meaning with respect to the 100% complementarity
18:08:01 22 because the 12 consecutive bases supplies that
18:08:07 23 functionality. That's just not correct. The claim term
18:08:11 24 requires 100% complementarity, and that can go beyond the 12
18:08:15 25 consecutive bases, it's not just those bases. It says at

18:08:20 1 least those 12 bases but is also 100% complementary. So
18:08:23 2 more than the 12 bases of seek ID can be 100% complementary,
18:08:27 3 so that term is not superfluous under our reading.

18:08:31 4 Further, the particular embodiments that are
18:08:35 5 recited in the specification, preferred embodiments do not
18:08:39 6 fit into that claim language. The specification
18:08:43 7 specifically contemplated antisense oligonucleotides that
18:08:49 8 are not 100% complementary. It says that flat out, that the
18:08:53 9 antisense oligonucleotides of the claim that are in the
18:08:58 10 specification need not be 100% complementary.

18:09:01 11 My colleagues also mentioned WEASEL. It
18:09:04 12 includes WEASEL embodiments that would not be within their
18:09:09 13 reading. So we have at least six canons of claim
18:09:14 14 construction that Judge Williams relied on that are violated
18:09:17 15 by a construction that conflates the antisense
18:09:20 16 oligonucleotides with a 100% complementary base sequence
18:09:26 17 that spans the entirety of the antisense oligonucleotides.

18:09:30 18 And this is the portion of the specification
18:09:32 19 that I was referring to. It says, "An antisense molecule
18:09:37 20 need not be 100% complementary."

18:09:40 21 This is also consistent with Dr. Dowdy, --
18:09:44 22 Dr. Dowdy's subsequent opinions where he says that he
18:09:46 23 recognizes that antisense and base sequence are separate.
18:09:53 24 So he's going to construe antisense on top of base sequence
18:09:58 25 and say that the term "antisense" carries with it a

18:10:02 1 complementarity requirement.

18:10:04 2 And he acknowledges that even under his POSA's
18:10:08 3 definition, that the antisense oligonucleotide can tolerate
18:10:13 4 one or two mismatches. So that would be inconsistent with
18:10:16 5 the finding that the claims require 100% complementary.

18:10:19 6 THE COURT: You agree that antisense
18:10:21 7 oligonucleotides is a limitation, though, right? The
18:10:23 8 preamble is limiting.

18:10:26 9 MS. WILLIAMSON: It was our position that it was
18:10:28 10 not, but if Your Honor -- if Your Honor is inclined to
18:10:32 11 determine that it is, we can live with that. And we think
18:10:35 12 it can be separately construed and it can preserve the
18:10:38 13 meaning that both of the parties have based their expert
18:10:42 14 reports upon.

18:10:43 15 You know, at this stage, to be clear, I don't
18:10:47 16 think that either party has properly opined on a scope of
18:10:52 17 the claims that's limited to only 100% complementary
18:10:56 18 antisense oligonucleotides. We would be highly prejudiced
18:11:00 19 by going to trial on the current set of opinions because
18:11:02 20 they just don't address that construction. They address a
18:11:06 21 construction where the base sequence is 100% complementary.

18:11:11 22 And Dr. Dowdy has given further opinions that it
18:11:14 23 should be limited to up to what we think is four mismatches,
18:11:18 24 based on his deposition testimony.

18:11:21 25 Dr. Hastings has responded that in her practice,

18:11:24 1 she has sought patents on antisense oligonucleotides that
18:11:28 2 are up to 70 percent complementary, so 30 percent
18:11:33 3 noncomplementary.

18:11:33 4 So there's a dispute in the record amongst the
18:11:36 5 experts on okay, yes, we agree that not all antisense
18:11:40 6 oligonucleotides are 100% complementary. That's well known
18:11:44 7 and agreed to. But in the record, there's a factual dispute
18:11:49 8 about the level of complementarity that is necessary.

18:11:52 9 And I think if Your Honor is going to issue a
18:11:55 10 clarification, it should be to that term, "antisense
18:12:01 11 oligonucleotides," not a disruption of Judge Williams'
18:12:05 12 construction about the base sequence, which for the reasons
18:12:08 13 I've said is legally correct.

18:12:09 14 THE COURT: Well, what's the jury even going to
18:12:11 15 take from it, I guess is what I'm wondering? So again, I
18:12:15 16 don't want to beat a dead horse here, but he says -- the
18:12:21 17 Court says, "A base sequence means any sequence of bases
18:12:25 18 that's part of the antisense oligonucleotides."

18:12:28 19 How does a jury understand that that means it
18:12:31 20 can include -- right. It can have a part that is 100%
18:12:36 21 complementary to consecutive bases in the target region and
18:12:40 22 a part that can't. I mean, it's your expert that is going
18:12:42 23 to say that, but his construction doesn't say that.

18:12:48 24 MS. WILLIAMSON: I'm sorry, Your Honor, could
18:12:49 25 you repeat --

18:12:50 1 THE COURT: Yeah, I'm just sort of saying we
18:12:52 2 all, for those of us who have some experience in this
18:12:56 3 technology, we all understand what the dispute here is, but
18:12:58 4 the jury is not going to understand that based on this claim
18:13:02 5 construction is all I'm saying.

18:13:03 6 MS. WILLIAMSON: So I think what we'd say is
18:13:05 7 it's a portion. What Judge Williams says is it's -- the
18:13:09 8 base sequence has certain requirements. And here there's
18:13:12 9 really -- there's no actual dispute on infringement, so we
18:13:14 10 don't have to confuse the jury with any kind of
18:13:17 11 infringement.

18:13:17 12 THE COURT: Thank goodness for that.

18:13:19 13 MS. WILLIAMSON: Really, the only thing that we
18:13:21 14 are discussing with the jury that relies on -- that relies
18:13:27 15 on the term "antisense oligonucleotides" now is how large is
18:13:31 16 the genus, what kind of genus are we talking about?

18:13:34 17 THE COURT: Right. And so your expert says it
18:13:36 18 has at least two billion compounds because it can include
18:13:41 19 these random sequences on the end. And then their expert
18:13:44 20 says no, it's really only 2,000 compounds. And then your
18:13:48 21 expert says, you know what, even if it's only 2,000, it
18:13:53 22 still fails for lack of written description and lack of
18:13:56 23 enablement.

18:13:56 24 So you have an opinion on if it's only 2,000,
18:13:59 25 right?

18:13:59 1 MS. WILLIAMSON: Correct. The amount is not
18:14:02 2 2,000, but we have an opinion under Dr. Dowdy's
18:14:05 3 construction. And we're willing to go forward on that and
18:14:09 4 clarify the construction in a way that will frame that issue
18:14:12 5 for the jury in terms of -- in terms of putting bounds on
18:14:18 6 the genus.

18:14:19 7 THE COURT: So I guess my question is, if I
18:14:22 8 don't let NS argue to the jury that this construction that
18:14:29 9 Judge Williams gave you -- or maybe I even clarify it, that
18:14:32 10 says what this doesn't mean is that you can have a part
18:14:35 11 that's complementary and then a whole part that's not at
18:14:38 12 all. If I don't let you say that, you still have a position
18:14:41 13 under 112 and you can move forward with the trial next week?

18:14:44 14 MS. WILLIAMSON: So, as the experts have opined
18:14:47 15 on it so far, Dr. Dowdy's position is that, you know, he
18:14:54 16 construed base sequence and he said, okay, fine, that's 100%
18:14:58 17 complementary. But look here at antisense oligonucleotides,
18:15:02 18 that has to be 100% complementary or highly complementary.

18:15:06 19 If that is the construction that Your Honor
18:15:10 20 adopts or the clarification that you adopt, then the experts
18:15:13 21 have opined on it and our expert has an opinion. And
18:15:16 22 there's a factual dispute about what that highly
18:15:20 23 complementary area would mean.

18:15:22 24 THE COURT: Right.

18:15:22 25 MS. WILLIAMSON: Excluding that highly

18:15:24 1 complementary area from the construction is contrary to the
18:15:26 2 specification, because the specification indication
18:15:29 3 expressly allows for not 100% complementary.

18:15:33 4 All of the experts agree that there are many
18:15:35 5 reasons for mismatches and other things in the design of
18:15:38 6 antisense oligonucleotides.

18:15:40 7 And so just as a matter of science, requiring a
18:15:44 8 hundred percent complementary is not the -- and in NS's
18:15:48 9 respectful view is not the correct response to the ambiguity
18:15:51 10 that might be in the base sequence of the claim.

18:15:58 11 So we would propose that we construe antisense
18:16:00 12 oligonucleotides. We have proposed -- we are proposing now.

18:16:06 13 THE COURT: And then are you going to put on --
18:16:08 14 if we do it that way, Dr. Hastings is not going to say
18:16:12 15 there's two billion species in the genus, right?

18:16:16 16 MS. WILLIAMSON: Correct.

18:16:17 17 THE COURT: And there's not going to be any
18:16:18 18 discussion about "and so, therefore, the Court's base
18:16:22 19 sequence can allow all this other different stuff too"?

18:16:26 20 I'm just trying to figure out how we can fix
18:16:29 21 this without digging a bigger hole or restarting all the
18:16:32 22 expert reports. I understand perfectly what happened here.

18:16:35 23 Is there a path forward?

18:16:36 24 MS. WILLIAMSON: Yes. I think there is. So the
18:16:38 25 construction we would now propose is an antisense

18:16:43 1 oligonucleotide that binds to a pre-mRNA target with
18:16:50 2 sufficient complementarity to avoid nonspecific binding.

18:16:54 3 This is the wording from the specification.

18:16:56 4 Dr. Dowdy relies on this wording in formulating his opinion
18:17:01 5 that an antisense molecule is highly, if not 100%
18:17:06 6 complementary. We think it would be proper or more proper
18:17:09 7 to go to the words of the specification and construe
18:17:12 8 complementarity in this manner.

18:17:14 9 And so there has to be sufficient -- so it would
18:17:17 10 take care of Your Honor's concern that there's this enormous
18:17:21 11 amount of random -- I'm not sure if you said random stuff
18:17:25 12 but --

18:17:25 13 THE COURT: Right. We all understand. Yeah.
18:17:27 14 But I guess it wouldn't take care of their concern that
18:17:29 15 really it needs to be 100%, and they want me to tell the
18:17:33 16 jury that it's 100%.

18:17:35 17 MS. WILLIAMS: But that's not what they said in
18:17:38 18 their MIL. They said they wanted 100% or nearly 100%. They
18:17:43 19 never argued. That was today that they've argued -- they're
18:17:46 20 rearguing claim construction that was done --

18:17:49 21 THE COURT: At my request. At my request
18:17:52 22 because I'm scared that I'm seeing these MILs flying back
18:17:55 23 and forth. And I can resolve them in a way that I think
18:17:57 24 would fix things but might just be digging a deeper hole and
18:18:01 25 then we're going to waste our time next week. And that's

18:18:04 1 what I'm worried about.

18:18:05 2 And so I understand your point. Your expert was
18:18:08 3 in bounds in terms of how they understood what Judge
18:18:11 4 Williams did. If I tell the jury that this requires 100%
18:18:17 5 complementarity because of the language of the claim, and I
18:18:19 6 understand that you disagree with that, do you have a 112
18:18:23 7 defense? What does that do to your expert's ability to
18:18:26 8 opine on 112?

18:18:28 9 MS. WILLIAMSON: We have a 112 defense, but we
18:18:30 10 would need to go back to the board and reformulate it.

18:18:34 11 Because the things we focused on in our expert reports were
18:18:37 12 not what we would focus on if we had been talking about 100%
18:18:40 13 complementary. It's just an entirely different inquiry for
18:18:44 14 us to understand the scope of the claim. The genus would
18:18:48 15 still be quite large.

18:18:49 16 THE COURT: Right. Still 2000, somewhere close
18:18:52 17 to.

18:18:52 18 MS. WILLIAMSON: It's actually quite a bit
18:18:58 19 larger, because we -- and --

18:19:01 20 THE COURT: At least 2000.

18:19:04 21 MS. WILLIAMSON: It's at least 2000 but there
18:19:06 22 are many issues we did not address in our expert reports,
18:19:09 23 changes in different backbone chemistry and other chemical
18:19:14 24 modifications and other things, just because it was not as
18:19:18 25 important.

18:19:18 1 THE COURT: Because you had the 1 in 2 million.

18:19:22 2 And I totally understand that.

18:19:22 3 MS. WILLIAMSON: It was qualitatively unfair for
4 to -- to be forced to go forward without redeveloping, and
18:19:26 5 redoing expert reports on the scope of the genus under a new
18:19:28 6 claim construction and it really would be an entirely new
18:19:31 7 and different claim construction in a reversal of what Judge
18:19:35 8 Williams would do.

18:19:36 9 So I would urge the Court to find a middle
18:19:39 10 ground or even to adopt what Dr. Dowdy is now arguing, that
18:19:44 11 we can resolve this by looking at what is an antisense
18:19:47 12 molecule and what does a POSA believe that that requires.

18:19:52 13 So he says, "1 to 4 mismatches."

18:19:54 14 Our expert says somewhere in the area of 1 to 6
18:19:58 15 mismatches -- if we can go to that.

18:20:07 16 This is from one of the patents, the Bestwick
18:20:10 17 patents that Sarepta's expert relies on in his report. In
18:20:15 18 the specification, it talks about preferably 645,321
18:20:21 19 mismatches. So this is a very, very common scientifically
18:20:25 20 acceptable point of view for what an antisense
18:20:30 21 oligonucleotide is.

18:20:32 22 THE COURT: And understood. Again, maybe if we
18:20:35 23 change the base sequence construction. So I think I hear
18:20:43 24 what you're saying, which is, if the Court clarifies Judge
18:20:53 25 Williams' claim construction and essentially reverses his

18:20:55 1 his reasoning behind it, that you would not be prepared to
18:20:59 2 go forward next week?

18:21:00 3 MS. WILLIAMSON: That's correct.

18:21:01 4 THE COURT: All right. Let me hear from the
18:21:04 5 other side. Just on the issue --

18:21:08 6 MS. WILLIAMSON: Sorry, I just wanted to --

18:21:10 7 THE COURT: You want to finish your --

18:21:12 8 MS. WILLIAMSON: Oh, no. That's okay. I just
18:21:13 9 wanted to make sure to mention that its still our position
18:21:16 10 that the base sequence would be in the preamble.

18:21:19 11 MR. SIKORA: So, in other words, Your Honor --

18:21:21 12 THE COURT: That the preamble would be limiting?

18:21:24 13 No.

18:21:24 14 MR. SIKORA: So there are actually three
18:21:26 15 different interpretations that are floating around. One is
18:21:29 16 what Jude Williams adopted, which is only the base sequence
18:21:32 17 has a complementary limitation and the preamble is
18:21:36 18 nonlimiting.

18:21:37 19 The one that counsel argued today is that the
18:21:39 20 entire antisense oligonucleotide is exactly 100% and the one
18:21:44 21 that we were proposing, that they argued in the motion in
18:21:48 22 limine, that Dr. Dowdy is arguing for, is that the entire
18:21:51 23 thing is mostly that the base sequence is 100. That's the
18:21:55 24 one that we were proposing.

18:21:56 25 THE COURT: Right. Fully understand. Yep.

18:22:09 1 MR. RAICH: So, I think first of all, that the
18:22:13 2 claim should be construed ultimately just based on what is
18:22:17 3 the proper construction of the term. It's not ultimately a
18:22:21 4 question of what's convenient, it's what is the appropriate
18:22:25 5 construction? And so we do think that base sequence needs
18:22:30 6 to be looked at very carefully and very closely. I think
18:22:33 7 that's the first thing.

18:22:36 8 Dr. Dowdy, in talking about the meaning of
18:22:40 9 antisense was operating under the Court's construction. And
18:22:43 10 so when Dr. Dowdy said that there could be a mismatch in the
18:22:48 11 context of an oligonucleotide, that was operating under the
18:22:53 12 construction that we were operating under, but he also
18:22:57 13 performed calculations in terms of the scope of the genus,
18:23:02 14 in the context of the report where there was 100%
18:23:09 15 complementary, which is essentially what we are adopting as
18:23:11 16 the base sequence.

18:23:12 17 THE COURT: So you're ready to go forward next
18:23:14 18 week, but they're not.

18:23:17 19 MR. RAICH: Well, respectfully, I think that
18:23:18 20 they are, because first of all, they responded at least to
18:23:21 21 doctor -- as I said before, they have other sort of theories
18:23:24 22 of the case that aren't just based on the scope of the
18:23:32 23 genus. And as sort of an additional point, you know, I
18:23:39 24 heard Ms. Williamson state that they would agree with --
18:23:45 25 there's a new construction that they -- it's the first time

18:23:47 1 that we've heard about it, that wasn't set forth in any of
18:23:51 2 their expert reports.

18:23:51 3 THE COURT: I'm sure they were thinking about it
18:23:53 4 all weekend because I -- to be this late -- and on Friday.

5 MR. RAICH: Understood. Understood.

18:23:56 6 THE COURT: So I'm not blaming them for that.

18:23:58 7 MR. RAICH: They said that Dr. Dowdy, you know,
18:24:01 8 agreed with having four mismatches in an oligonucleotide. I
18:24:08 9 also don't think that's correct. And I heard in argument,
18:24:10 10 going back to the base sequence, about how we're reading out
18:24:14 11 comprising from the claim because it's a comprising claim.

18:24:18 12 And antisense oligonucleotide has different
18:24:22 13 parts to it. It has a base sequence, it has a chemical
18:24:26 14 backbone that supports the bases and holds them in place.
18:24:30 15 It may have a modification at the end, like a tail it's
18:24:35 16 called. And so we're not reading out comprising. It's an
18:24:40 17 antisense oligonucleotide with the base sequence, whatever
18:24:43 18 those bases are, is 100% complementary over the full length.

18:24:47 19 And then there are additional parts other than
18:24:50 20 the base sequence such as the particular chemical backbone.
18:24:54 21 That's why comprising is appropriate there.

18:24:59 22 THE COURT: So -- and I get the point on claim
18:25:01 23 construction. I'm trying to think of the most efficient way
18:25:05 24 to go forward. This Court's construction of "base sequence"
18:25:13 25 doesn't tell the jury really one way or the other anything

18:25:16 1 about the dispute we're talking about here, does it?

18:25:19 2 MR. RAICH: You're right. It's sort of
18:25:23 3 interpreting it in the broader context of the claim and what
18:25:26 4 the effect of it is. So I think it's almost like you have
18:25:28 5 to explain what the dispute is to even understand the effect
18:25:32 6 of the construction. So I do agree with that.

18:25:35 7 THE COURT: And so the plaintiff has proposed
18:25:38 8 that we go -- we let the jury hear the case and I'm going to
18:25:44 9 give the construction, which they haven't asked for a
18:25:48 10 clarification of. They can tell the jury, what this means
18:25:50 11 is, you can hook on -- a bunch of junk onto the end and that
18:25:54 12 that still falls within the Court's claim construction.

18:25:56 13 You want to be able to say, it doesn't or you're
18:26:00 14 happy with letting that go forward and then you-all can talk
18:26:04 15 to the jury about what antisense oligonucleotide means and
18:26:08 16 it means it can have up to four mismatches.

18:26:11 17 You want to be able to go forward or you want me
18:26:14 18 to tell the jury that this has to be 100% complementary?

18:26:18 19 MR. RAICH: I think from our perspective, saying
18:26:22 20 something other than 100% complementary would ultimately be
18:26:29 21 improper, but I also think the case is primed to go forward
18:26:33 22 because Dr. Hastings has offered additional opinions that
18:26:38 23 relate to things other than just the scope of the genus.

18:26:44 24 As I mentioned before, there is arguments that
18:26:46 25 she makes about things in the specification. So I think

18:26:53 1 that the case is primed to go forward and that it should do
18:26:56 2 so with the appropriate construction.

18:26:59 3 MR. MORIN: May I add something, Your Honor? I
18:27:01 4 don't mean to play two-on-one kind of thing but may I add
18:27:04 5 something just --

6 THE COURT: Sure.

18:27:05 7 MR. MORIN: -- just from the perspective of
18:27:06 8 sitting in that chair.

18:27:08 9 I want to reemphasize something that Mr. Raich
18:27:11 10 said, which is, we think that the clear construction of the
18:27:19 11 term requires 100% complementary bases. And we think that
18:27:24 12 ultimately, respectfully, to Judge Williams, that the folks
18:27:31 13 in Washington, we think are going to see it that way. I
18:27:34 14 think Your Honor should respectfully construe the claim the
18:27:37 15 way the claim is correct.

18:27:38 16 And if our friends need more time, I understand
18:27:41 17 that putting off a trial is drastic remedy, but if they
18:27:46 18 think they need more time in view of that construction, that
18:27:49 19 is the more efficient way to deal with things and we get it
18:27:53 20 right and we come back and we do it. It's never the first
18:27:57 21 choice of anybody obviously.

18:27:59 22 But, it is a -- the most important thing is
18:28:03 23 to -- and we think Your Honor has identified -- potentially
18:28:06 24 an issue that we felt very strongly about the first time
18:28:09 25 around, when they say anything about what Dr. Dowdy did,

18:28:12 1 it's obviously operating under what Judge Williams said was
18:28:15 2 the construction of the claim. He had to do with it what he
18:28:17 3 could, which he did. But anything saying it could be nearly
18:28:21 4 100% was in the context of the ruling on base sequence
18:28:25 5 already that he was required to operate under. And we told
18:28:27 6 them that that's a fixed body.

18:28:29 7 But if it would mean that, it would mean that,
18:28:32 8 but the important thing is to get it right now, Your Honor.

18:28:35 9 THE COURT: All right. Appreciate it. I hope
18:28:37 10 everyone understands, I didn't mean to cutoff anyone's
18:28:40 11 *Markman* arguments. I can assure you, I'm fully aware of
18:28:44 12 everyone's positions. We've poured over the *Markman*
18:28:48 13 briefing. We've reviewed the patents. We've reviewed Judge
18:28:53 14 Williams' claim construction order. I'm worried about
18:28:59 15 digging a deeper hole than what I think we might already be
18:29:02 16 in, but I'm not prepared to make a final decision on what
18:29:08 17 should be done.

18:29:09 18 I am hearing from plaintiff, though, that if the
18:29:12 19 Court is inclined to tell the jury that base sequence
18:29:21 20 requires 100% complementary, that plaintiff needs more time.

18:29:29 21 It looked to me from the expert reports like
18:29:33 22 there was a 112 defense still in there, but I can't -- let
18:29:43 23 me put it this way: I can't understand plaintiffs' point
18:29:46 24 that they would have emphasized different things in the
18:29:49 25 expert report. And I appreciate that.

18:29:54 1 So I guess we should have addressed this right
18:29:58 2 at the outset. So why don't we all sleep on it and I'll
18:30:04 3 sleep on it. I am in the middle of another trial right now.
18:30:10 4 We'll work as hard as we can at night and during breaks to
18:30:14 5 see if we can come up with an answer.

18:30:16 6 I have to tell you, as you might have guessed,
18:30:18 7 my inclination is that there does need to be a clarification
18:30:23 8 or a change to Judge Williams' base sequence claim
18:30:26 9 construction. And what my experience has told me, is that
18:30:37 10 going to the jury trial and hoping things work out, doesn't
18:30:40 11 actually work the way you think it's going to work and that
18:30:44 12 wasting people's time, if you're going to ultimately change
18:30:47 13 something later, is not a preferred course of action.

18:30:52 14 So those are my thoughts on that. And I realize
18:30:57 15 that the outcome of that has to do with how we're going to
18:31:02 16 rule on No. 3, as well as whether we're going to have the
18:31:06 17 trial at all.

18:31:07 18 So we do need to give the court reporter a break
18:31:10 19 because she has now been going for nine hours, transcribing.
18:31:14 20 So let's proceed this way. We're going to work on what we
18:31:18 21 think about the claim construction. It doesn't sound like
18:31:23 22 we have agreements between the parties about how we could
18:31:27 23 potentially proceed with the expert reports we have, but I'd
18:31:29 24 like you to continue to talk. And if somebody thinks of an
18:31:32 25 idea of how we might go forward, I'm happy to hear it

18:31:36 1 because we have you on the calendar and we moved a lot
18:31:39 2 around to get everybody to trial next week, despite being
18:31:42 3 only assigned this case a few weeks ago.

18:31:49 4 Why don't we plan to have a letter from the
18:31:55 5 parties by Wednesday evening. Just telling us if there's
18:32:11 6 been any change to their position, again, the position that
18:32:13 7 I'm hearing from plaintiffs is that, if there's a change to
18:32:17 8 the claim construction, that we need to redo the expert
18:32:20 9 reports.

18:32:21 10 And defendants' position, that we could move
18:32:24 11 forward based on what we have so far. And then we'll have a
18:32:28 12 status call Thursday at 10 a.m. and we'll put the number on
18:32:37 13 the court's line. And then if we're going to move forward,
18:32:42 14 we'll discuss the rest of the issues in the pretrial order,
18:32:49 15 none of which were all that challenging and we're ready to
18:32:54 16 tell you what our rulings are on those.

18:32:57 17 I hate to leave it up in the air like this for a
18:33:02 18 couple of days but this is where we're at. Does anybody
18:33:05 19 have a better idea?

18:33:06 20 MR. MORIN: I don't. I wanted to address just a
18:33:08 21 couple things, Your Honor, hopefully in the sake of
18:33:11 22 efficiency. I know it's late.

18:33:12 23 The first is, there was a dispute between the
18:33:15 24 parties about the number of hours for the bench trial on
18:33:18 25 unenforceability. And we figured we would tell you what we

18:33:21 1 told our friends just before this hearing.

18:33:24 2 We've decided not to pursue our unenforceability
18:33:27 3 claim against them. We looked at it and decided it was
18:33:31 4 redundant with the obviousness claim and it will arise or
18:33:34 5 fall -- we think rise -- with our obviousness arguments, but
18:33:37 6 since they were somewhat redundant in what the result was
18:33:41 7 going to be, that we would take that off the table, which I
18:33:44 8 think means the competing proposals, them for four hours per
18:33:48 9 side and us for two would be cut in half. So half of that
18:33:52 10 will happen then. So hopefully that's welcome news for the
18:33:56 11 Court on that front.

18:33:57 12 I should also advise the Court that we have not
18:34:00 13 yet resolved the breach of contract issue. We're optimistic
18:34:05 14 we will. Compared to the patent issues, it's very low -- I
18:34:07 15 won't say the amount, but a very low -- very, very low
18:34:11 16 amount compared to the other main issues in the case. We
18:34:14 17 have a proposal out to them.

18:34:15 18 Reasonably, their folks are on Golden Week, so
18:34:20 19 they haven't been able to respond. We're hoping to take it
18:34:23 20 off your table but our friends propose -- and we are not
18:34:26 21 contesting that -- if that still remains, which we're very
18:34:29 22 optimistic it won't, again, it's a small amount, that with
18:34:34 23 Your Honor's blessing, we would do it while the jury is
18:34:37 24 deliberating a week from Friday and no more than one hour
18:34:40 25 per side.

18:34:41 1 We think it may be 15 or 20 minutes, it's very
18:34:43 2 little, we think, on that. But we agree with our friends
18:34:46 3 that if it's not resolved with the Court's blessing, we
18:34:50 4 would do it that Friday.

18:34:51 5 One other thing that I'm hesitant, I know you
18:34:54 6 want to get out of here, but we have -- our friends brought
18:34:59 7 up an issue percolated by an e-mail from them last Tuesday,
18:35:03 8 that has to deal with some standing and damages issues, that
18:35:07 9 they would like -- we think we're still fine but they would
18:35:10 10 like some expedited briefing on this week.

18:35:14 11 And they proposed -- and I think they were going
18:35:16 12 to propose that they would file a brief tomorrow and we
18:35:19 13 would file a response on Wednesday. I only say that because
18:35:21 14 if the Court were inclined to postpone the trial and pick
18:35:25 15 another day, this expedited briefing on damages and standing
18:35:29 16 and stuff could be dealt with in a more deliberate and
18:35:34 17 considered fashion.

18:35:37 18 It has to do with an issue they raised last
18:35:40 19 Tuesday. We identified some additional agreements in
18:35:43 20 response to that that hadn't been produced that we did
18:35:48 21 produce and investigation and discussions have been going on
18:35:50 22 kind of nonstop to kind of bring it to Your Honor in a
18:35:54 23 reasonable way.

18:35:55 24 But later in your cross, the issue of the claim
18:35:58 25 construction, it might be a prudent decision for us to be

18:36:03 1 able to take sometime for the briefing and the discovery of
18:36:07 2 the information for Your Honor rather than have layering on
18:36:10 3 top of your other bench trial and these claim construction
18:36:14 4 issues in these other briefs, sets of briefs on this new
18:36:17 5 issue where they are now contending, as far as I can tell
18:36:20 6 that there's a standing and a damages issue and we are going
18:36:23 7 to be opposing that.

18:36:24 8 A little bit of daylight before people are all
18:36:28 9 in town from the other people and a little daylight to come
18:36:32 10 and try this case once both the claim construction issue is
18:36:36 11 resolved and that's resolved, might be a more prudent way to
18:36:40 12 do things. I say that not lightly. Trial dates being moved
18:36:43 13 are -- I know Your Honor had to move things around, like you
18:36:46 14 said, and everybody does and the clients and the witnesses
18:36:49 15 and I appreciate that but we want to get it right, Your
18:36:52 16 Honor.

18:36:52 17 So I only raise that so it's not a surprise to
18:36:55 18 Your Honor.

18:36:56 19 THE COURT: All right. Thank you very much.

18:36:57 20 MR. SIKORA: Your Honor, just a quick point of
18:37:00 21 clarification, because when somebody says "standing," that
18:37:03 22 usually implicates a bigger deal.

18:37:05 23 Our current understanding is there's at least a
18:37:08 24 13-month period within the damages period in which the
18:37:11 25 Sarepta Therapeutics entity, the plaintiff on their patent

18:37:16 1 claims in the lawsuit, lost exclusive rights.

18:37:17 2 And so that's our current understanding. It's
18:37:20 3 still evolving. The agreements weren't produced during
18:37:24 4 litigation. They involved internal transfer with Sarepta.
18:37:27 5 We're prepared to go forward on briefing what we think the
18:37:30 6 issue is, including the discovery issues and the failure to
18:37:32 7 disclose those timely tomorrow by 5 p.m.

18:37:36 8 Sarepta agreed to their responsive brief, a
18:37:41 9 5-page letter brief by Wednesday of the same and so we're
18:37:45 10 happen to do that if Your Honor is willing to entertain that
18:37:49 11 briefing.

18:37:49 12 THE COURT: Counsel?

18:37:51 13 MR. MORIN: As we indicated to our friends, we'd
18:37:53 14 be willing on that briefing schedule but I guess what I'm
18:37:56 15 saying is --

16 THE COURT: I understand, yeah.

18:37:57 17 MR. MORIN: -- there's a lot of moving parts and
18:37:58 18 if you have to deal with 5 p.m. and 5 p.m. on damages being
18:38:01 19 changed, also in addition to the claim construction and he
18:38:05 20 says he doesn't see a standing issue, but we heard issues of
18:38:10 21 when exclusivity was, which --

18:38:12 22 THE COURT: I understand. So here's what I'll
18:38:14 23 say: I'm not going to decide the damages issue if we're not
18:38:17 24 going forward with the trial next week. I'm not going to
18:38:20 25 decide it on Thursday night. So with that in mind, I'm

18:38:24 1 hearing from plaintiffs that maybe you need to talk to your
18:38:28 2 people and confirm about whether or not you want to go
18:38:31 3 forward if the Court is inclined to change the claim
18:38:34 4 construction or amend the claim construction.

18:38:36 5 And so if you know that you're not going to go
18:38:38 6 forward, you don't have to file your damages brief when
18:38:42 7 you've agreed with them, but you have to tell them you're
18:38:45 8 not planning on going forward. Does that make sense?
18:38:47 9 Otherwise, we're going to proceed with the briefing.

18:38:49 10 MR. SIKORA: And just to clarify, Your Honor.
18:38:52 11 Our view was that if the interpretation from Dr. Dowdy in
18:38:56 12 his report of some number of mismatches but not the full,
18:38:59 13 everything, if the construction advanced by them in their
18:39:05 14 expert reports was the one -- the middle ground that we
18:39:09 15 referred to, if that was adopted by the Court clarifying the
18:39:13 16 preamble term antisense, we would be prepared to go forward
18:39:17 17 next week. It's simply if Your Honor reversed Judge's
18:39:20 18 Williams entirely, that we would more time.

18:39:24 19 And that is what we obviously contend is the
18:39:24 20 correct result and the one that we think the folks in
18:39:29 21 Washington would agree with.

18:39:31 22 THE COURT: Right.

18:39:32 23 MR. MORIN: Thank you, Your Honor.

18:39:34 24 THE COURT: Okay. I guess we'll talk to
18:39:37 25 everybody on Thursday. I didn't take any of this lightly.

18:39:40 1 I hope everyone knows. We'll work as hard as we can to get
18:39:44 2 you an answer.

18:39:45 3 MR. MORIN: We appreciate your Honor's time.

18:39:49 4 COURT CLERK: All rise.

18:39:52 5 (Court adjourned at 6:39 p.m.)

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10 I hereby certify the foregoing is a true and
11 accurate transcript from my stenographic notes in the
proceedings.

12

/s/ Stacy M. Ingram, RPR
Official Court Reporter
U.S. District Court

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